EXHIBIT 53

EXPERT REPORT OF JOSEPH T. RANNAZZISI

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This Report Relates To:

Case No. 1:18-op-45817-DAP

JANUARY 24, 2024

Executive Summary

Plaintiff Cobb County, Georgia has asked me to provide an opinion regarding the distribution practices of Kroger and Publix. The issues examined specifically concern their policies and procedures with respect to maintaining effective control against the diversion of pharmaceutical opioids during the period from 2006 to 2014 and beyond.

Cobb County is located in the Atlanta Metropolitan area in the north central portion of the state.[1] It is the third largest county with a population of 771,952.[2] There were approximately 204 retail pharmacies serving Cobb County during the ARCOS review period (2006 – 2014).[3]

As pharmaceutical opioid distributors, Kroger and Publix are required to maintain effective controls against diversion, including establishing a system to monitor and detect suspicious orders of controlled substances and conducting due diligence sufficient to dispel any suspicion associated with those orders. For the reasons discussed more fully herein, Kroger and Publix each failed to fulfill their obligations by instituting ineffective diversion control programs, thereby creating conditions that allowed diversion and over-supply of opioids in Cobb County, Georgia. Based on my review as described herein, Defendants failed to fulfill their obligation to maintain effective controls against the diversion of pharmaceutical controlled substances during the applicable time period through their failure to design and operate suspicious order monitoring programs ("SOMs") in a manner reasonably calculated to detect and stop suspicious orders. As a result, together they caused, and were a substantial factor in causing, the pharmaceutical opioid epidemic in Cobb County.

Qualifications

I retired from the Drug Enforcement Administration ("DEA") Senior Executive Service with over 29 years of federal law enforcement experience as a special agent/investigator. I conducted and supervised multi-jurisdictional, multi-target criminal, civil, and regulatory investigations throughout my career. Prior to my retirement in October 2015, I was responsible for oversight and control of all regulatory compliance inspections and investigations, as well as all civil and criminal investigations, of approximately 1.6 million DEA registrants, supervising an authorized workforce of 225 employees, 81 contractors, and controlling an operating budget of approximately $356 million. I was the principal DEA liaison to law enforcement and regulatory agencies at the federal, state and local levels concerning the diversion and illegal distribution of controlled pharmaceuticals and listed chemicals, the clandestine manufacture of controlled substances, and the trafficking and abuse of synthetic drugs.

I am a nationally- and internationally-recognized speaker on controlled substance pharmaceuticals and performance enhancing drugs, pharmaceutical diversion investigations, security, abuse trends, regulatory compliance, listed chemicals and synthetic drugs. I have provided training concerning illicit drugs, pharmaceuticals, pharmaceutical control, security, chemicals, synthetic drugs and clandestine laboratories to hundreds of audiences representing law enforcement personnel, attorneys and judges, professional organizations, pharmaceutical industry executives and employees, community groups, Congress, government officials, and international partners (including Canada, China, Mexico, and Turkey) that represented law enforcement, compliance, and regulatory control agency counterparts.

In my position prior to retirement in 2015, I provided regulatory oversight and supervised the inspection and investigation of businesses that import, export, manufacture, distribute or dispense

[1] https://en.wikipedia.org/wiki/Cobb_County,_Georgia.
[2] https://www.georgia-demographics.com/counties_by_population.
[3] SLCG, Opioid Shipments to Pharmacies in Cobb County, Georgia retail (ARCOS DATA).

controlled substances and listed chemicals to ensure compliance with regulatory requirements related to drug and facility security, recordkeeping, and accountability. These regulatory investigations included on-site inspection and review of physical security controls and procedures employed at DEA-registered controlled substance manufacturing and distribution sites throughout the United States. I evaluated registrant violations and, when appropriate, issued Orders to Show Cause ("OTSC") to initiate administrative proceedings to revoke or suspend registrations to handle controlled substances, and I approved Immediate Suspension Orders ("ISO"). I was designated as the U.S. Competent Authority for controlled substances and listed chemicals, and I supervised U.S. representatives attending meetings organized by the International Narcotics Control Board and the Commission on Narcotic Drugs.

I received my pharmacy degree from Butler University College of Pharmacy in 1984, and I have been a licensed pharmacist in the State of Indiana since 1984. In October 2014, I received an Honorary Doctor of Pharmacy License from the Oklahoma State Board of Pharmacy. In 2015, the National Association of Boards of Pharmacy ("NABP") awarded me the Lester E. Hosto Distinguished Service Award for unwavering dedication to protecting the public health and significant involvement with the NABP and its initiatives. This award is the highest honor bestowed by NABP. Throughout my career, I have lectured at several colleges of pharmacy, including Butler University, Creighton University, Massachusetts College of Pharmacy, University of Mississippi, University of Tennessee, and University of Texas at Austin; and I have provided pharmacy continuing education in numerous states, to include Arizona, California, Florida, Illinois, Indiana, Kentucky, Maine, Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, Ohio, Oklahoma, Texas, Utah, Virginia, Washington, and Wisconsin.

A detailed history of my experience and qualifications is contained in Appendix A.

Methodology

I reviewed each Defendant's policies, processes and procedures that the defendants claim were designed to meet their obligation to maintain effective controls against diversion. This included a review of each Defendant's SOM program in effect during the relevant time period and documents related to those SOM programs, related deposition testimonies, and other relevant documents provided to me as noted herein. Among the documents and materials I have reviewed to prepare this report, I reviewed deposition transcripts from this Cobb County litigation, deposition transcripts of Defendants from the MDL proceeding, and if available, deposition transcripts of Defendants from other state court opioid litigation. I reviewed Cobb County's Complaint. I reviewed documents produced by Defendants, the DEA, and other third parties. I am being compensated at a rate of $500 per hour regardless of the outcome of this litigation.

I was deposed by counsel in the MDL2804 litigation on April 26, 2019, May 15, 2019, September 22, 2021. I was deposed in opioid-related litigation brought by the State of Ohio on July 16 and 17, 2020, and by counsel in litigation brought by ACE American Insurance Company on January 19, 2022. I was also deposed in opioid-related litigation brought by various hospitals located in the State of Alabama on May 25, 2023. On February 22, 2020, I provided an expert report and opinions in opioid-related litigation in *State of Ohio v. McKesson Corporation, et al,* Case No. CVH20180055. On March 24, 2023, I provided an expert report and opinions in opioid-related litigation in *State of Nevada v. McKesson Corp., et al*, Case No. A-19-796755-B. I testified in opioid-related litigation involving two counties in the State of West Virginia on June 7-10, 2021; involving two counties in the State of Ohio on October 12-13, 2021, and involving the State of Florida on April 18-19, 2022. Finally, I provided an expert report on August 22, 2022, and I was deposed on December 14, 2022, in opioid-related litigation brought by Montgomery County, Ohio (MDL-CT7).

Overview of the Controlled Substances Act

To understand the basis for my opinions herein, it is first necessary to understand the requirements of the Federal Controlled Substances Act ("CSA") and applicable regulations, as well as the responsibilities of DEA-registered entities.[4]

The Closed System of Distribution

The responsibility to regulate the safety, efficacy, purity, and marketing of pharmaceuticals, in general, rests with the U.S. Food and Drug Administration ("FDA") pursuant to the authority provided in Title 21 U.S.C., Chapter 9 (Federal Food, Drug, and Cosmetic Act or "FDCA"). However, Congress recognized that the subset of pharmaceuticals identified as controlled substances requires additional regulatory oversight and scrutiny that is not necessary for non-controlled substances because of the potential for dangerous adverse health consequences associated with abuse and misuse that can affect public health and safety.[5] Therefore, Congress enacted the Federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.* The CSA was designed to halt "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[6] When discussing controlled pharmaceuticals, the term "diversion" refers to the movement of legitimately manufactured drug products, generally controlled substances such as opioids[7] or anxiolytics, from the licit supply chain to the illicit market.

The CSA: (1) defines and categorizes substances into five schedules of control; (2) specifies the qualifications of those individuals and entities that may be authorized to handle controlled substances; (3) provides a process to establish limits on the amount of certain pharmacologic classes and schedules of controlled substances that may be produced; (4) requires specific recordkeeping related to the handling of controlled substances; (5) authorizes DEA to enter and inspect registered locations (i.e., the physical locations where controlled substances are stored, manufactured, distributed, or dispensed); (6) allows DEA to promulgate methods for lawful public disposal and create a pharmaceutical waste disposal

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[4] While the foregoing sections outline in detail the requirements of the Federal Controlled Substances Act, many states across the United States, including Georgia, have adopted statutes incorporating these legal requirements and/or imposing state law requirements that are identical or substantially similar to the CSA. *See* O.C.G.A. § 16-13-1, *et seq.* (Georgia Controlled Substances Act); O.C.G.A. § 16-13-36 (registration in Georgia is contingent upon a distributor's maintenance of effective controls against diversion of controlled substances); Ga. Comp. R. & Regs. 480-7-.03(10) (distributors must comply with applicable federal law and DEA regulations specifically); Ga. Comp. R. & Regs. 480-20-.02 (distributors shall maintain records of unusual orders of controlled substances received and shall inform GDNA of unusual orders when discovered; an unusual order shall include orders of "greatly increased quantity, orders deviating substantially from a normal pattern, and orders of highly abnormal frequency"); O.C.G.A. § 26-4-115 (automatically submit to GDNA reports of excessive purchases of controlled substances using the DEA guidelines set forth in 21 CFR § 1301).

[5] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the ... [CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.").

[6] H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572. *See* Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Before the Subcommittee on Health, Committee on Energy and Commerce, US House of Representatives, for a hearing entitled, *"Improving Predictability and Transparency in DEA and FDA Regulation"* (April 7, 2014). https://www.congress.gov/113/chrg/CHRG-113hhrg90872/CHRG-113hhrg90872.pdf (accessed July 7, 2022).

[7] For this report, the term "opioid" refers to all pharmaceuticals in the class of drugs (natural, semi-synthetic and synthetic) that produce morphine (opiate-like) effects when ingested, are structurally similar to natural opiates, and produce similar pharmacologic properties of opiates through interaction with opiate/opioid receptors. Opioids are sometimes referred to as "narcotic drugs," a term defined at 21 U.S.C. § 801(17) and used to describe a broader class of drugs that includes cocaine. In contrast, an "opiate" is a natural product (alkaloid) derived from the opium poppy plant *(Papaver somniferum*) to include codeine, morphine, and thebaine.

infrastructure in the United States; (7) mandates reporting of certain transactions/events involving controlled substances; and (8) imposes security requirements that protect controlled substances as they are manufactured, stored, distributed, dispensed, or otherwise transferred or disposed of. Together, these specifications create an infrastructure that has been described as the "closed system of distribution" for all controlled substances. They maintain integrity within the supply chain—from the point of import or manufacture, to distribution, and ultimately, to dispensing to the patient or destruction.

The following graphic illustrates the statutory and regulatory components of the CSA's closed system of distribution: schedules, registration, quota, recordkeeping, inspections, disposal, reporting, and security. Components relevant to the Defendants' obligations are also discussed below.

Drug Schedules

The foundation of control in the CSA is the classification of controlled substances into one of five "schedules." A drug is placed into an assigned schedule based upon whether it has a currently accepted medical use in treatment in the United States, the potential for abuse of the substance relative to substances in other schedules, and the level of physical or psychological dependence (severe, moderate or low) that may result from abuse of the drug.[8] Schedule I controlled substances have no accepted medical use in the United States, have the highest potential for abuse, and lack accepted safety for use under medical supervision.[9] Heroin, fentanyl analogues such as acetyl fentanyl and LSD are Schedule I controlled substances. Schedule II through V controlled substances have an accepted medical use and, as the numeric schedule increases, there is a comparatively decreasing potential for abuse and physical/psychological dependence that may result from abuse of the drug.[10] For example, cocaine, oxycodone, and hydrocodone products have an accepted medical use (or have an accepted medical use with severe restrictions) but also have a high potential for dependence and abuse so they are all placed in

[8] 21 U.S.C. § 812(b); see also 21 CFR part 1308 (identifying all controlled substances by drug code and listing additional scheduled drugs).
[9] 21 U.S.C. § 812(b)(1).
[10] 21 U.S.C. §§ 812(b)(2)-(5).

Schedule II. Similarly, Schedule III drugs, such as combination codeine products, have less potential for abuse than drugs in Schedule II, and a lower potential for physical dependence.

Varying degrees of statutory and regulatory requirements apply to each numeric schedule, e.g., prescribing, physical security, and reporting requirements are more stringent for Schedule II substances than for Schedule III substances.

For example, in October 2014, hydrocodone was transferred from Schedule III to Schedule II based on a scientific and medical review of the drug using the statutory 8-Factor analysis that included:

1. The drug's actual or relative potential for abuse
2. Scientific evidence of the drug's pharmacological effects, if known
3. The state of current scientific knowledge regarding the drug or other substance
4. Its history and current pattern of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled

Based on this scientific and medical analysis, DEA, with the concurrence of FDA, placed all hydrocodone products in Schedule II, which better reflected the potential for abuse, and physical and psychologic dependence properties of the drug. As a Schedule III drug, hydrocodone could be prescribed with up to five refills and could be prescribed by telephone to the patient's pharmacy. As a Schedule II drug, it could not be prescribed with refills and could only be dispensed pursuant to a written and signed paper prescription or via electronic prescribing ("EPCS") if permitted by the applicable state. Up-scheduling was a message to prescribers and pharmacists that hydrocodone was a very potent opioid that should be treated with the same level of care as other Schedule II opioids such as morphine and oxycodone.

Registration

The CSA requires registration with the DEA to ensure that only those who are authorized by the United States and the individual states (if required) can import, manufacture, distribute, dispense,[11] and research with controlled substances.[12] The CSA provides distinct registration requirements for each type of entity that desires to handle controlled substances.

Distributors will be registered unless their registration is inconsistent with the "public interest."[13] The following factors must be considered when determining the public interest: "(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels; (2) compliance with applicable State and local law; (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution or dispensing of

[11] "The term dispense means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance…" 21 U.S.C. § 802(10). Registered pharmacies may dispense controlled substances to patients pursuant to valid prescriptions, and other registered entities such as clinics and hospitals may dispense directly to patients based upon the lawful order of a registered practitioner without the requirement of a valid prescription.
[12] 21 U.S.C. §§ 822(a), 957.
[13] 21 U.S.C. §§ 823(b) and (e), 824(a)(4).

such substances; (4) past experience in the distribution of controlled substances; and (5) such other factors as may be relevant to and consistent with the public health and safety."[14]

Similarly, manufacturers will be registered if it is consistent with the public interest and U.S. international obligations.[15] Registered manufacturers may distribute controlled substances pursuant to their manufacturer registrations and are required to follow the same laws and regulations applicable to distributors when they engage in distribution activities.[16]

Practitioners, including physicians, mid-level practitioners (e.g., advanced practice nurses, physician assistants) and pharmacies will be registered if they are authorized by their state to dispense controlled substances, unless it is inconsistent with the "public interest."[17] The following factors are considered when determining the public interest: "(1) [t]he recommendation of the appropriate State licensing board or professional disciplinary authority; (2) [t]he applicant's experience in dispensing, or conducting research with respect to controlled substances; (3) [t]he applicant's conviction record under Federal or State laws relating to the manufacture, distribution or dispensing of controlled substances; (4) [c]ompliance with applicable State, Federal or local laws relating to controlled substances; [and] (5) [s]uch other conduct which may threaten the public health and safety."[18]

Once an entity is appropriately registered with DEA, revocation or suspension of registration may be appropriately based upon consideration of certain enumerated factors.[19] For registered distributors and practitioners such as pharmacies, those factors include a finding that the registered entity has: (1) materially falsified an application; (2) been convicted of a felony relating to controlled substances or list I chemicals; (3) had his State license or registration suspended, revoked, or denied by competent State authority; (4) committed such acts as would render his registration inconsistent with the "public interest" as described above; or (5) been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.[20]

Recordkeeping

Every DEA registrant is required to maintain records that are specific to their registration business activities. Recordkeeping and inventory requirements ensure accountability through auditing. See 21 U.S.C. § 827 (records and reports of registrants); 21 U.S.C. § 828 (order forms); 21 U.S.C. § 829 (prescriptions); 21 CFR part 1304 (Records and Reports of Registrants); 21 CFR part 1305 (Orders for Schedule I and II Controlled Substances); 21 CFR part 1306 (Prescriptions).

Reporting: Automation of Reports and Consolidated Orders System ("ARCOS")

The CSA requires registered manufacturers and distributors to periodically report to the DEA all transactions involving narcotic controlled substances, among others.[21] ARCOS is the DEA system that receives and stores this transaction data. The data reported includes information pertaining to the acquisition and distribution of controlled substances between manufacturers and distributors, and from

[14] 21 U.S.C. §§ 823(b) and (e).
[15] 21 U.S.C. §§ 823(a) and (d), 824(a)(4).
[16] 21 CFR §1301.13(e) (stating that a manufacturer is authorized to distribute any controlled substance that the manufacturer is registered to manufacture, so long as they comply "with all requirements and duties prescribed by the law for persons registered to engage in such coincident activities").
[17] 21 U.S.C. §§ 823(f), 824(a).
[18] 21 U.S.C. § 823(f).
[19] See 21 U.S.C. § 824.
[20] 21 U.S.C. § 824.
[21] 21 U.S.C. § 827(d); 21 CFR § 1304.33.

manufacturers and distributors to pharmacies, hospitals, and other practitioners that dispense to patients. ARCOS does not maintain information regarding pharmaceuticals dispensed to patients.

ARCOS data is reported to DEA quarterly, in general.[22] Once reported, the data must be validated and if necessary, corrected and re-submitted. Accordingly, it can be up to six months before the information can be used to reliably determine where certain controlled substances were distributed. In other words, it is not "real time" information.[23]

Security

A foundational principal of the closed system of distribution is security, specifically the requirement that **all** applicants and registrants maintain an effective system—controls and procedures—to guard against the theft and diversion of controlled substances.[24] Each registrant must comply with the security requirements set forth in 21 CFR §§1301.71-1301.77, which were designed to help the registrant maintain effective controls against diversion. In fact, 21 CFR § 1301.71(a) specifically states, "In order to determine whether a registrant has provided effective controls against diversion, the Administrator **shall** use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls **and operating procedures necessary** to prevent diversion."[25] In evaluating a registrant's overall security system, DEA may consider the "adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations."[26]

Suspicious Orders

A key component to the reporting and security requirements is the requirement to design and operate a system to detect and disclose to the registrant suspicious orders, which "*…include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*"[27] Furthermore, *"[t]he registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.*" 21 CFR § 1301.74 (b). Therefore, in order to comply with the requirement to maintain effective controls against diversion, distributors must identify and report suspicious orders when discovered.

I am aware that some distributors coin phrases, such as "order of interest," to signify controlled substance orders subject to preliminary review for suspicion. In my opinion, any mechanism or process designed to detect orders that are of "unusual size," "unusual frequency," or "deviate substantially from a normal pattern" is designed to detect "suspicious orders." Therefore, an order characterized as an "order of interest" or other term by such a mechanism or process is a "suspicious order" that cannot be distributed unless the suspicion is dispelled, and the order must be reported to the DEA and the state, if applicable, when discovered.

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[22] 21 CFR § 1304.33(b).
[23] In contrast, suspicious orders must be reported to DEA "when discovered." 21 CFR § 1301.74(b); see also 21 U.S.C. § 832(a) (2018 amendment requiring suspicious order reports "upon discovering").
[24] 21 CFR § 1301.71(a); 21 U.S.C. §§ 823, 824.
[25] 21 CFR § 1301.71(a) (emphasis added).
[26] 21 CFR § 1301.71(b)(14).
[27] 21 CFR § 1301.74(b); see *Masters Pharmaceutical, Inc. v DEA*, 861 F.3d 206 (D.C. Cir. 2017) (holding that the regulations describing suspicious orders provides illustrative examples, and that other indicia may also raise suspicions about an order for controlled substances); *Southwood Pharmaceuticals, Inc., Revocation of Registration*, 72 Fed. Reg. 36487 (July 3, 2007); *Morris & Dickson Co., LLC; Decision and Order*, 88 Fed. Reg. 34523 (May 30, 2023).

Notice of Obligations

Defendants were well aware of their obligations with respect to suspicious orders.

The laws and regulations requiring distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances,[28] the requirement to report the suspicious orders to DEA when discovered by the registrant,[29] and the requirement that distributor registrants maintain effective controls against diversion of controlled substances into other than legitimate, medical, scientific and industrial channels,[30] have all been in place since the CSA was passed as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the regulations promulgated pursuant to the Act in 1973.

DEA Letters to Manufacturers and Distributors

In September 2006, the DEA Office of Diversion Control sent a letter to all entities registered with DEA as a distributor or a manufacturer that reinforced the requirements of the statutory scheme and legal duties of distributors as DEA registrants, highlighting the suspicious order requirement and circumstances that may be indicative of diversion. Additionally, the DEA cautioned registrants stating:

> Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration. In a similar vein, given the requirement under Section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as Section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.[31]

In February 2007, DEA sent another letter to manufacturer and distributor registrants reiterating the responsibilities of controlled substance manufacturers and distributors concerning suspicious orders and again explaining the expectations of DEA in the identification and reporting of these orders. [32]

On December 27, 2007, DEA sent a follow-up letter to manufacturer and distributor registrants reiterating the responsibilities of controlled substance manufacturers and distributors concerning suspicious orders and further explaining the expectations of DEA in the identification and reporting of these orders. The letter pointed out that the regulation (21 CFR § 1301.74(b)) "clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications

[28] See 21 CFR § 1301.74(b).
[29] Id.
[30] See 21 U.S.C. § 823(b)(1); 21 U.S.C. § 823(e)(1).
[31] CVS-MDLT1-000010552; ABDCMDL00269691 (Letter from Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi dated September 27, 2006).
[32] WMT_MDL_000145329-32 (Letter from DEA Deputy Assistant Administrator Joseph Rannazzisi dated February 7, 2007).

with DEA, whether implicit or explicit, that could be construed as approval of a particular system reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[33]

The letter also reinforces the requirement of suspicious order reporting when discovered and dispels the notion that monthly excessive purchase reports or "high unit purchases" can substitute for a system that reports suspicious orders when discovered. The letter also stated: "Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."[34]

The letter also discussed the disjunctive nature of the suspicious order definition and indicated that the definition is not all inclusive. The letter stated: "The size of the order alone, whether or not it deviates from a substantial ordering pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry."[35]

The letter also discussed why reliance on rigid formulas to detect suspicious orders may actually fail to detect suspicious orders. Using an example of monthly increased sales by percentage as the sole criteria, the letter cautioned that, "This system fails to identify [suspicious] orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor." The letter also cautioned registrants that reporting suspicious orders and then filling them without resolving the suspicion behind the order, "*may be failing to maintain effective controls against diversion.*"[36]

Finally, this letter directed the registrants to review the final order in the case of *Southwood Pharmaceuticals Inc*., 72 Fed. Reg. 36487 (July 2007), that described in detail the obligation to report suspicious orders, identified some criteria useful in determining whether an order is suspicious, and emphasized the registrant's obligation to maintain effective controls against the diversion of controlled substances. This final order detailed the distribution activities of Southwood Pharmaceuticals that resulted in the revocation of its registration, including the repeated distribution of controlled substances such as hydrocodone (at that time a Schedule III controlled substance) to customers that they knew, or should have known, were diverting the substances through internet sales, and an explanation of why Southwood Pharmaceuticals' due diligence efforts were insufficient.[37]

DEA took action against the three largest controlled substance distributors in the United States, McKesson, Cardinal Health, and AmerisourceBergen—known as the "Big 3"—who continued to fulfill orders that they knew or should have known were suspicious, contrary to their legal obligations under the CSA. The Big 3 were all involved in widely publicized administrative and civil investigations that led to civil fines, memorandums of agreement, and compliance agreements. Some of the distributors involved in these investigations had their registrations revoked/suspended for a period of time prohibiting them

[33] KrogerSmithNMAG000003203; ABDCMDL00269685 (Letter from Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi dated December 27, 2007 to all DEA manufacturer and distributor registrants).
[34] Id.
[35] Id.
[36] Id (emphasis added).
[37] Id.

from distributing controlled substances from certain facilities. In 2012, Walgreens also faced enforcement action related to its distribution activities. DEA alleged that Walgreens failed to detect and report suspicious orders by its own pharmacies and that Walgreens failed to conduct adequate due diligence of its retail stores. In 2013, Walgreens agreed to settle the allegations against it, acknowledging that suspicious order reporting for distribution to certain pharmacies did not meet the standards reinforced in the three letters sent by DEA to all manufacturers and distributors in 2006 and 2007.

Several years later, some distributors were again administratively and civilly charged with supplying pharmacies that were filling unlawful prescriptions, despite the memorandums of agreement and compliance agreements with the government and their prior assurances that they would comply with the suspicious order monitoring and reporting requirements of the CSA and implementing regulations, and that they would maintain effective controls against diversion.

Responsibilities of Registrants

The United States has been in an opioid crisis for more than two decades and attention is rightly focused on how the healthcare delivery system will do its part to abate the addiction, overdose, and death that have resulted. Indeed, every member of the healthcare delivery system and supply chain has a part to play and those that manufacture, distribute, dispense, and prescribe should ensure that they are doing everything possible to prevent opioids and other controlled substances from fueling this epidemic.

Distributors

The CSA and implementing regulations provide specific requirements and impose certain compliance obligations to be followed by distributors to ensure that diversion is identified and stopped.

Effective Due Diligence

Due diligence is "such a measure of prudence, activity, or assiduity, as is properly to be expected from, and ordinarily exercised by, a reasonable and prudent man under the particular circumstances; not measured by any absolute standard, but depending on the relative facts of the special case."[38] The term "due diligence" is not described in the CSA or its implementing regulations, however, it is established that distributors are required to conduct due diligence in order to maintain effective controls against diversion, i.e., to first determine whether an order is "suspicious," and if so, to take appropriate action to dispel the suspicion before fulfilling the order.[39]

In order to maintain effective controls against diversion, a reasonably prudent controlled substance distributor's due diligence effort will constantly gather and accumulate information and evaluate the following components: the customer, the order, and the surrounding conditions. When information regarding the three components is thoroughly considered, a controlled substance distributor may make a reasonable determination, based on all the facts gathered for each component, whether the order is suspicious, whether to distribute the order to the pharmacy customer, and whether to report the order to the appropriate authorities.

The Customer

[38] Black's Law Dictionary 457 (6th ed. 1991).
[39] See *Southwood Pharmaceuticals, Inc., Revocation of Registration*, 72 Fed. Reg. 36487 (2007); *Masters Pharmaceutical, Inc. v DEA*, 861 F.3d 206 (confirming that the regulations mandate that pharmaceutical companies exercise due diligence before shipping any suspicious order); *Morris & Dickson Co., LLC; Decision and Order*, 88 Fed. Reg. 34523 (2023).

The reasonable distributor's SOM program appropriately evaluates a pharmacy applicant and establishes a profile of an applicant before approval as a customer. Reasonable due diligence starts with a trained employee reviewing information about the business, and an on-site visit to discuss and verify application information. The facts gathered regarding the customer should include, but are not limited to: the pharmacy's business model, ownership information, dispensing data, prescriber data, and ordering history. Customer information can be obtained from external sources such as the relevant state Board of Pharmacy, the relevant state Board of Medicine, local crime reports, federal databases and websites and other publicly available information; and from internal sources such as surveillance visits, on-site visits, and questionnaires. Of paramount importance is independent verification or corroboration of information provided by the pharmacy customer.

More detailed information about the pharmacy customer will include: location (e.g., rural or urban), population of area, licensing (state pharmacy license and DEA registration), how long it has been in business at that location, names of owners, pharmacists and technicians (and a determination regarding disciplinary actions and law enforcement encounters), previous suppliers, size of prescription volume, controlled to non-controlled volume, medical facilities, clinics and hospitals in the area, estimation of controlled substance orders per month by basic class and how that compares to other customers in the area and average customer in the state or geographic region (if the estimated need is above average, documented and verified justification), identification of controlled substance prescribers in the area and the pharmacy's primary controlled substance prescriber(s) and their specialties. Other areas of consideration include, but are not limited to:

- Whether the pharmacy fills or intends to fill prescriptions from out-of-state doctors and if so, how many and from what states;

- Whether the pharmacy regularly fills prescriptions from prescribers that are located outside a reasonable commuting distance from the pharmacy or patients who live outside a reasonable commuting distance from the pharmacy or the prescriber, and if so, volume and relevant information regarding the prescribers;

- Whether the pharmacy fills prescriptions for suspect combinations of drugs including opioids, benzodiazepines and muscle relaxants, and if so, the volume and relevant prescribers;

- Whether the pharmacy is affiliated with a pain clinic or pain doctor that directs all of his/her patients to the pharmacy; and/or

- Whether the pharmacy dispenses medications via a website.

Responses to the above queries may necessitate further inquiry. The applicant should provide at least six months of dispensing records to show dispensing of all drugs in that time period; the distributor should note the top drugs dispensed. The on-site visit is an opportunity to visually inspect the pharmacy while conducting an in-person review of the application and getting answers to additional or follow-up questions.

A reasonable controlled substance distributor will obtain information about each pharmacy to which it distributes controlled substances. A pharmacy's operating status as an independent or a chain, by itself, is not the deciding factor in the due diligence analysis. So too, the responsibility to conduct due diligence and to identify and report suspicious orders is that of the distributor, and that responsibility cannot be delegated or abrogated simply because the pharmacy customer is a chain, or because the distributor is a pharmacy chain that self-distributes.

The Order

The facts gathered regarding the order include, but are not limited to: the drug types and strengths requested, single order volume anomalies, a comparison to other orders from the customer, like pharmacies or customer base, and any other information available to help determine whether it meets the illustrative criteria for suspicion (i.e., unusual size, frequency, or deviate substantially from a normal pattern). The reasonable distributor's SOM will identify orders for additional review based on criteria reasonably calculated to detect the potential for diversion.

Threshold Criteria

A threshold is "a level, point, or value above which something is true or will take place and below which it is not or will not."[40] Thresholds are not required features in a SOM, but they can be used in different ways to help distributors identify orders for additional review.[41] For example, highly complex systems may be designed to use variable algorithms incorporating data from several sources (e.g., dispensing data, prescriber data, sales data, geographic and demographic data, community information, retailer data, historical ordering patterns individually and within a cohort, drug trend data, and other relevant factors) to evaluate incoming orders for size, frequency, or deviation, and to identify orders that require further detailed analysis, information collection, or investigation.

Complex systems may analyze the data collected and then focus on any number of the following non-exhaustive criteria to set a variety of reasonable thresholds:

- Meeting or exceeding a reasonable basic class threshold;
- Meeting or exceeding a threshold for a certain drug product and dosage strength (e.g., oxycodone 30 mg);
- Single high-volume orders that are under a numerical threshold but still unusual in size or deviate substantially from a pattern;
- Anomalies with respect to a particular controlled substance or combinations thereof, e.g., a shift to high dosage formulations, a combination of different classes of controlled substances such as benzodiazepines and muscle relaxants, or a shift in orders of a high volume of only one controlled substance;
- Purchases of high dose/strength formulations when compared to lower strength formulations, e.g., oxycodone 30 mg compared to oxycodone 5 mg;
- Increasing the frequency of orders for specific drug/strength, including high dosage formulations, within a specified time frame; and/or
- Patterns in the ratio of controlled substance purchases versus non-controlled substance purchases.

[40] Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/threshold.
[41] For circumstances that may be indicative of diversion, as well as a variety of inquiries that can help to determine whether an order is suspicious, see Letter from Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi dated December 27, 2007; Letter from DEA Deputy Assistant Administrator Joseph Rannazzisi dated September 27, 2006.

Customer-specific thresholds for a basic class would incorporate the information gleaned during the on-boarding due diligence review (as described herein), e.g., the type and size of the pharmacy, at least six to nine months of dispensing data, an estimate of anticipated monthly dispensing by basic class and how that estimate and dispensing data compare to a pharmacy of similar size and similarly situated to the applicant customer and the average customer within the same demographic and geographic location, including state and local community demographics and geographics. A reasonable threshold would also incorporate a method to avoid "threshold creep" and to prevent use of inflated, historical ordering patterns that do not reflect current ordering patterns, such as re-evaluation of customer thresholds at least annually.

A reasonable distributor would not only look at the basic class but would also review high dose formulations within the class to determine if a particular customer is placing orders of a high dosage strength drug when compared to other customers of the distributor in a particular area. A reasonable threshold system should also incorporate review of specific high abuse dosage forms of a particular class of drugs, as necessitated by drug trends. For example, hydrocodone 10 mg, and oxycodone 15 mg and 30 mg immediate release products were commonly prescribed by rogue pain clinics/rogue doctors to drug seekers/abusers in Georgia and across the United States. Therefore, in Georgia it would be reasonable to review orders for anomalies or patterns related to hydrocodone 7.5 mg and 10 mg, as well as high dose oxycodone products (i.e., oxycodone 10 mg, 15 mg and 30 mg).

In another example, in September/October 2010, Purdue Pharma released a new OxyContin product (oxycodone extended release) featuring a delivery system that was touted as discouraging abuse. These tablets were supposed to be extremely difficult to breach, crush or pulverize to snort, smoke, or inject the oxycodone within the drug. The new OxyContin product could still be abused when taken orally but many drug seekers desired the instant rush/euphoria experienced by the routes of administration that the new delivery system was designed to defeat. Drug seekers turned to high dose oxycodone tablets (10 mg, 15 mg, and 30 mg) that did not have an abuse deterrent delivery system in order to continue to abuse oxycodone in ways other than the oral route. Accordingly, ordering patterns that reflect large orders of oxycodone 40 mg and 80 mg tablets before 2010 followed by a noticeable decrease of orders in 2010 and 2011 is consistent with pharmacy dispensing activity that caters to customers involved in diversion and abuse of controlled substances. The suspicious activity is further supported by a large order increase for oxycodone 15 mg and 30 mg tablets which correspond to the order decrease in oxycodone 40 mg and 80 mg.

In contrast to the above noted complex threshold systems, other systems may be designed to simply measure whether incoming orders exceed a pre-determined quantity, or a variable quantity based on historical ordering.

The effectiveness of a threshold can be measured by how accurately it identifies orders that are of unusual size, frequency, or deviate substantially from a normal pattern.[42] A threshold that solely identifies orders based on a pre-determined quantity is not an effective tool to help monitor or detect suspicious orders. First, it would fail to identify orders that are suspicious on the basis of unusual frequency or because they deviate substantially from a normal pattern. These two factors are just as important as unusual size is in maintaining effective controls against diversion. Second, if the threshold is set arbitrarily or unreasonably high, it will fail to identify orders that are below the threshold quantity but are comparatively unusual in size. Third, quantitative thresholds can be easily circumvented if they are known to the purchaser. And last, quantitative thresholds are easily subject to "threshold creep," i.e., slowly increasing purchases over short periods time.

[42] See 21 C.F.R. § 1301.71(a) ("In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion").

Regardless of how threshold criteria are constructed, the effectiveness of a distributor's SOM program also depends on what takes place if the threshold is reached.

The Conditions

The facts gathered regarding the conditions include, but are not limited to: whether there is any reasonable explanation for recent changes in ordering and whether those same forces are having a similar effect on surrounding pharmacies; geographic data and demographics, community information, changes in drug seeking behavior and related diversion trends, and general information about the diversion of controlled substances such as commonly abused drugs and drug combinations, drug trends such as the OxyContin reformulation and its impact on drug-seeking behavior, pending up-scheduling or new controls, changes in patterns of prescribing, and reports of drug abuse and drug trends published by law enforcement and regulatory agencies (e.g., National Threat Assessment, Regional Threat Assessment, local/state threat assessments, department of health assessments, etc.).

Evaluation of a Suspicious Order

Once a monitoring system signals the potential for a suspicious order (e.g., a threshold is triggered), an in-depth due diligence evaluation must be undertaken by an employee who has the appropriate training to evaluate the order. The order must be evaluated taking into account information about the customer, the order, and the circumstances, including but not limited to information gleaned as a result of the due diligence performed during on-boarding, information developed during the course of the business relationship, the history of ordering patterns of the basic class of drug involved, any changes reflected in the pharmacy's dispensing data and an on-site visit. A system designed to detect the potential for diversion will independently verify or corroborate any facts that clarify the suspicion, and appropriately document those facts; it would also do so with respect to raising thresholds. An important part of the due diligence evaluation is review of the pharmacy customer's dispensing practices, the pharmacy's history, including ordering history but also prior statements in any on-boarding inquiries, on-site investigations, information regarding the surrounding area, and any related pharmacy information or investigations. This is why it is vitally important for distributors to maintain due diligence-related information and data cumulatively, for the duration of the distributor relationship.

Independent review is paramount to the process. A reasonable distributor would ensure that the reviewers are not involved, directly or indirectly, in sales or marketing and that the reviewers cannot be influenced by salespeople who are naturally focused on maintaining the pharmacy as a customer. The independent evaluation includes determining whether the order is indeed suspicious or if there is a reasonable explanation that can resolve the suspicious nature of the order.

An unresolved suspicious order cannot be shipped. Any suspicious orders that are shipped are in violation of the law. Accordingly, a distributor that continues to unreasonably raise thresholds, or continues to raise thresholds in the absence of reasonable justification, is motivated by a desire to circumvent the law with respect to detecting and reporting suspicious orders.

Reporting a Suspicious Order

As discussed, suspicious orders must be reported to the DEA and the state (if required), regardless of the term any particular distributor ascribes to it (e.g., "order of interest," "excessive order," "irregular order"). For example, if a threshold is designed to detect anomalies related to unusual size,

then orders that reach the threshold must be reported to the DEA. Failure to do so is subject to civil penalties.[43]

If the order is distributed after due diligence was performed and the suspicious nature of the order is resolved, a report does not have to be transmitted to DEA. However, a reasonable controlled substance distributor will maintain an accurate description of steps taken to resolve the suspicious nature of the order and the reason for the triggering event, a description of the due diligence performed, and how the distributor resolved the event and decided that the order would not be diverted. This information is important in understanding and resolving any future orders that may raise suspicion. A reasonable controlled substance distributor will also have protocols and procedures in place for the retention of records documenting threshold increases, the evaluation and resolution of suspicious orders, and the reporting of suspicious orders to DEA.

If a distributor determines that the order is suspicious after thorough consideration of all of the factors above, the distributor cannot distribute to the pharmacy. An unresolved suspicious order cannot be fulfilled or shipped and must be reported to DEA and the state (if applicable). Distributors that ship controlled substance orders that meet the definition of "suspicious order" without resolving the suspicious nature of the order fail to provide effective controls against diversion and the distributor is operating in violation of the statutory provisions of the CSA. The distributor may ship only when the distributor determines that the order is not suspicious (e.g., the distributor dispels any suspicion previously raised).

Practitioners[44]

Controlled substance prescribers and the pharmacies dispensing their prescriptions have a symbiotic relationship: appropriate pharmaceutical-based care of patients relies on both practitioners to perform their specific professional duties. Accordingly, they are intertwined in fact and in law.

Federal regulation specifies that only a pharmacist may fill a controlled substance prescription:

> A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.[45]

In addition:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the

[43] 21 U.S.C. §§ 842(a)(5), 842(c)(1)(B).
[44] For purposes of the CSA, a "practitioner" is a "'physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 21 U.S.C. § 802(21). A "mid-level practitioner" ("MLP") is an "individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." 21 CFR § 1300.01(b). Examples of MLPs include: nurse practitioners and physician assistants who are appropriately authorized to handle controlled substances.
[45] 21 CFR § 1306.06.

> prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[46]

Most prescribers adhere to the above legal requirements, however, there are prescribers who willfully, negligently, or recklessly disregard their ethical and legal obligations and issue prescriptions that are not for a legitimate medical purpose and not in the usual course of professional practice. There are also circumstances where a prescriber is duped or tricked by a patient seeking pain medications. The law relies on pharmacists receiving those illegitimate prescriptions *not* to fill them.

Common Ownership: Integration of Self-Distributing Corporations

As discussed, each entity that distributes controlled substances or dispenses controlled substances must be specifically registered to do so by the DEA and the state, as applicable. A registered distributor is not authorized to dispense controlled substances, and a registered dispenser (e.g., a pharmacy) is not authorized to distribute controlled substances.[47] Accordingly, when a pharmacy distributes to itself, for example by acquiring controlled substances directly from manufacturers for subsequent dispensing from its own pharmacy, it must obtain separate, independent DEA (and state, as applicable) registrations as a pharmacy and as a distributor, and must follow all of the laws and regulations applicable to both pharmacies and distributors, including but not limited to those related to suspicious order monitoring and reporting. Defendants Kroger and Publix participated in both pharmacy dispensing activities and controlled substance distribution activities (by distributing exclusively to their own branded stores) during the applicable time period.

As self-distributing corporations, Kroger and Publix were uniquely positioned to identify and stop the diversion of controlled substances. Unlike traditional distributors, they could monitor and control the dispensing activities at their pharmacies with no regard for the ambitions of profit-driven salespeople. At their distribution centers, they could design and implement strong and robust suspicious order monitoring and reporting programs and conduct in-depth, thorough due diligence investigations, including on-site visits and wide-ranging dispensing and prescribing reviews, due to their single corporate ownership and access to each of their pharmacy's controlled substance and non-controlled substance ordering and dispensing activities and records. This expansive access to a trove of information could provide corporate diversion/loss prevention employees and supervisors the ability to easily spot ordering pattern anomalies (i.e., unusual size, frequency or substantial deviation from a normal pattern) and enable them to query pharmacy employees and supervisors, district and regional managers, and if necessary, corporate leadership, to investigate any suspicion surrounding the orders. In other words, as distributors, they have the tools and the information necessary to monitor and detect suspicious orders and to conduct adequate due diligence. Likewise, Defendants' local, regional, and corporate pharmacy supervisors could be empowered to use distribution information, volume and type of controlled substances, and other ordering patterns as warnings that review of individual pharmacy dispensing activity is necessary to determine if

[46] 21 CFR § 1306.04(a) (emphasis added); see also *U.S. v. Moore*, 423 US 122 (1975).
[47] There is one exception commonly referred to as the "5% rule," where under certain circumstances a pharmacy may distribute up to 5% of its annual controlled substance inventory to another practitioner, ocean vessel, or aircraft without being registered as a distributor. *See* 21 C.F.R. §§ 1301.25(f), 1307.11.

corresponding responsibility/liability analyses are being performed in a manner consistent with Federal/State laws, regulations and appropriate pharmacy practice.

Given their common ownership, it would be reasonable to integrate corporate monitoring and due diligence data and activities with corresponding responsibility oversight and dispensing data in order to meet obligations to detect and prevent diversion. This in-house advantage should have resulted in the prompt removal of any obstacles to conducting due diligence sufficient to dispel any suspicion associated with orders. For example, suspicious order monitoring personnel should have easy access to dispensing records and activities when warranted by ordering anomalies. Corporate diversion and loss prevention personnel should be able to spot ordering anomalies quickly and be empowered to access pharmacy dispensing records and to query pharmacy personnel to clarify or dispel any suspicious ordering and purchasing patterns.

Instead, the opposite occurred. Rather than incentivizing their pharmacy personnel to self-monitor and self-correct their pharmacists' dispensing activities, Defendants Publix and Kroger compensated their personnel based on how well their stores performed—and performance was measured by how many prescriptions they filled.[48] The more prescriptions filled, the higher their compensation. Likewise, instead of prioritizing genuine due diligence investigations by diversion and loss prevention personnel, Defendants relegated the due diligence process to rote questions and answers and superficial, cursory review, if any. Notably, Defendants Kroger and Publix took this a step further and destroyed forms with historical information critical to conducting thorough due diligence. This created an environment where corporate supply chains gave little to no thought to diversion prevention.

As discussed above with respect to the due diligence process, independent evaluation of a controlled substance order is paramount to maintaining effective control against diversion. In guidance letters, DEA reminded all distributors that they "must conduct an *independent* analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels." It is important to emphasize that the corporate ties that enable unique access to ordering and dispensing information must not undermine independent, objective evaluation of the relevant facts and circumstances surrounding a potentially suspicious order.

Independent, objective evaluation requires self-distributing corporations to verify or otherwise corroborate information when appropriate. Information that generally cannot be validated by internal data streams include: the surrounding area (including other pharmacies and local prescribers/clinics), customer base, and justifications provided by pharmacies for increased ordering, unusual frequency in ordering, or a deviation from normal ordering patterns. In addition, critical information can be gained from on-site visits, for example: large groups of people waiting for their prescriptions to be dispensed; patients asking for tablets of a specific color or street name; numerous out-of-state cars in the parking lot; people passing off drugs in the parking lot; groups of people coming to the pharmacy at the same time; people being turned away at the pharmacy counter. While a system that allows for a robust analysis of distribution and dispensing data can identify potentially suspicious orders and prescriptions presented/dispensed in the presence of red flags, any distributor that relies solely on data streams or analytics to conduct due diligence, including self-distributing corporations, fails to have an effective system in place to identify and report suspicious orders.

[48] KrogerSmithNMAG00010074.

Diversion of Pharmaceutical Controlled Substances: Background

The term "diversion" refers to the movement of legitimately manufactured drug products, (i.e., pharmaceutical controlled substances—particularly opioids and anxiolytics), from the licit supply chain to the illicit market. The diversion of pharmaceutical controlled substances has occurred in many forms and schemes since the CSA was enacted in 1970. From the early 1970s until approximately the late 1990s, diversion was localized and involved practitioners (e.g., prescribers and dispensers), pharmacists, nurses, and others who were diverting controlled substances through self-abuse, prescription fraud, sex for drugs, illegal distribution (i.e., outright sale), theft, armed robbery, burglary, hijacking, and doctor shopping.

Historically, the individuals involved in controlled substance diversion and those ultimately receiving the drugs were generally confined to a city, county or region within a state. Pharmaceutical controlled substances were abused throughout the United States but not at epidemic levels. It was not common for drug seekers to seek pharmaceutical controlled substances from prescribers located several states away from their homes or through remote online ordering.

In 2008, medical clinics catering to pain patients began to appear in South Florida. By 2010, 142 clinics were located in Broward County, Florida alone and 941 were located in the entire state. Several other states reported pain physicians were operating clinics, but Florida by far had the largest concentration of pain clinics, and drug seekers began to travel to Florida to obtain pharmaceutical controlled substances such as opioids, benzodiazepines, and muscle relaxants. Although the clinics lacked the anonymity provided by the internet, it was almost guaranteed that if a person went to the clinic and paid the fee, that person would obtain the controlled substances requested. In contrast to internet transactions, drug seekers could get from pain clinics either oxycodone pills dispensed directly from the clinic or a prescription for oxycodone in addition to benzodiazepines and muscle relaxants. Additionally, other Schedule II drugs such as hydromorphone, methadone, and morphine could easily be obtained on request. Law enforcement and regulatory agencies reported that drug seekers from the Northeast and Midwest traveled to Florida and returned to their home states with multiple prescriptions for the same medication, visiting multiple clinics in a single trip. Millions of dosage units of oxycodone products were being diverted under the guise of medical care when in reality the clinics were just a new avenue for illegal drug distribution and a source for prescription opioids taken for a non-medical use or for sale/distribution in the illicit market.

The proliferation of pain clinics and indiscriminate prescribing was not limited to Florida, and the pharmacies filling these prescriptions were not limited to independent or regional pharmacies. Indeed, as revealed in *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*,[49] nationwide chain pharmacy corporations were responsible for significant diversion.

In the next section, I summarize my review of Kroger and Publix policies and procedures related to controlled substance distribution, specifically suspicious order monitoring and reporting. I provide my opinions regarding their effectiveness in detecting and preventing the diversion of controlled substances. My review shows that their SOM programs were ineffective at maintaining control against diversion and were ill-suited to detect and stop suspicious orders. My summary of each Defendant's programs highlights deficiencies I found during my review; however, the emphasis on one or more deficiencies is not intended to be exhaustive of the deficiencies found.

[49] 77 Fed. Reg. 62316 (Oct. 12, 2012).

Kroger: Diversion Control Policies and Procedures

Introduction

Kroger is a grocery/retail store chain headquartered in Cincinnati, Ohio that operates a nationwide retail pharmacy chain out of several subsidiary retail outlets including the Kroger retail supermarket chain. As of November 2020, Kroger operated 2,256 pharmacies located in combination food/drug stores.[50] The Kroger Company is one of the largest retailers in the world, as measured by revenue.[51]

From at least 2006 to 2014, Kroger self-distributed Schedule III through V controlled substances, including Schedule III HCPs, to its brand and affiliated/subsidiary retail pharmacies located in supermarkets throughout the United States. Kroger and its affiliated pharmacies were divided into divisions within the corporate structure. In 2014, three Kroger subsidiaries (i.e., Peyton Distribution Centers ("DCs")) distributed to 18 divisions of Kroger and its affiliated pharmacies.

Peyton Northern was located in Bluffton, Indiana, and distributed to 613 pharmacies located in the Cincinnati Division, Columbus Division, Michigan Division, Central Division, Mid-Atlantic Division, Jay C Division and Dillons Division. Peyton Southeastern was located in Cleveland, Tennessee, and distributed to 704 pharmacies in the Atlanta Division, Delta Division, Nashville Division, Mid-Atlantic Division and Southwest Division.[52] Peyton Southeastern and to a lesser extent, Peyton Northern, distributed Schedule III through V controlled substances to approximately 20 Cobb County, Georgia, Kroger Pharmacies from 2006 to 2019 (relevant ARCOS period).[53] During the relevant time period, both facilities were registered with DEA as a distributor of Schedule III through V controlled substances, and with the Georgia State Board of Pharmacy as a Pharmacy-Wholesaler-, under the name "Peytons Northern" in Bluffton, Indiana (License PHWH001216) and "Peytons Southeastern" in Cleveland, Tennessee (License PHWH001258).[54]

Peyton DCs only distributed controlled substances to Kroger and affiliated pharmacies and did not distribute controlled substances to any pharmacy outside of the Kroger corporate structure. During the relevant ARCOS reporting period, Cardinal Health distributed Schedule II controlled substances (including oxycodone, fentanyl, and hydromorphone) to Kroger pharmacies in Cobb County Georgia. When DEA transferred HCPs from Schedule III to Schedule II in October 2014, Cardinal Health began distributing HCPs to Kroger pharmacies throughout the United States, including Georgia. Cardinal Health also acted as a secondary distributor to Kroger pharmacies for Schedule III through V controlled substances during this time period.

In addition to being a registered distributor, Kroger was also a dispenser (retail pharmacy) of Schedule II through V controlled substances throughout the relevant ARCOS reporting period. A key in-house advantage to self-distributing is that there are few, if any, obstacles to obtaining detailed information to support a due diligence investigation and dispel (or confirm) any suspicions associated with an order. However, the methods ostensibly utilized by Kroger to monitor orders throughout most of the relevant ARCOS reporting period were inadequate to identify and stop suspicious orders and were therefore ineffective at maintaining effective control against diversion. As discussed below, Kroger's methods for monitoring orders, such as Inspector reviews, monthly post-shipment reviews, and maximum

[50] www.thekrogerco.com/about-kroger/our-business; see also SEC 10-K filed 3/29/2022 ("as of January 29,2022, Kroger operated, either directly or through subsidiaries 2,726 supermarkets of which 2,252 had pharmacies…").
[51] United States Securities and Exchange Commission, Form 10-K filed by the Kroger Company 3/29/2022.
[52] KrogerSmithNMAG00007980.
[53] A third DC, Peyton Phoenix, did not distribute to any of the Cobb County pharmacies during this time period.
[54] Georgia Board of Pharmacy – license verification and lookup.

order quantity ("MOQ") limitations, were poorly designed and implemented. When statistical thresholds were instituted in September 2013, Kroger was concerned that the number of "pended orders" (orders held until cancelled or released for shipment) was either too large or too small for the available resources, resulting in manipulation of the algorithm for the purpose of reaching a level of pended orders commensurate with available resources, rather than attempting to determine why their pharmacies were ordering controlled substances in quantities that met and exceeded the third-party recommended threshold for suspicion. Despite instituting a statistical threshold-based SOM program, I have not been provided with evidence that Kroger reported to DEA any suspicious orders originating from Kroger pharmacies in Cobb County, Georgia. In fact, the first suspicious order ever transmitted to DEA from a Kroger distribution facility occurred on October 23, 2013.[55] Even assuming that the statistical threshold method was sufficiently designed to identify suspicious orders, Kroger failed to implement and operate it in a manner that controlled against diversion.

In addition, Kroger failed to have the appropriate personnel, resources, or training to identify, hold, and investigate suspicious orders (i.e., conduct sufficient due diligence). The absence of formal operational policies, lack of adequate training and guidance, and limited resources and support throughout most of the reporting period created an environment that was conducive to controlled substance orders flowing through the system unchecked.

Policies and Procedures: Suspicious Order Monitoring System

Period 1: 2006-2013

Kroger asserts that prior to 2013 and the development and implementation of its statistical threshold, Kroger monitored orders submitted to its Peyton DCs. Further, Kroger asserts that when monitoring orders, it would collect and analyze the data pertaining to purchases using reports that were computer-generated at Kroger's Peyton DCs. Kroger maintains that its Peyton DCs would also report canceled orders to the DEA and, if requested, that Kroger would follow-up on any reports provided to the DEA.[56]

There may have been multiple mechanisms that monitored orders submitted to Peyton DCs, and my review revealed that these components did nothing more than monitor and track orders and, in the case of maximum order quantities, hold certain excess orders pending review. These methods appear to be designed as inventory management tools rather than as suspicious order monitoring tools. As documented later in this report, there was confusion among Kroger employees concerning the pre-2013 SOM program—none of them could adequately provide a description of the system or how it operated. There was no policy or procedure in place that outlined suspicious order monitoring and no formal written training or guidance to assist employees performing the review process (due diligence) or other guidance that provided objective criteria to assist employees in resolving or evaluating an identified order. None of these systems complied with the provisions of 21 CFR § 1301.74.

During Period 1, there appear to be three informal systems used to monitor orders at the DCs to include: Inspector review; White and Green Bar monthly reviews; and Maximum Order Quantities ("MOQ"). These components, ostensibly designed to identify, investigate, and report suspicious orders of controlled substances, were inadequate for the task and, in any event, appear to be post-hoc rationalizations for a SOM program pre-2013. Each of these processes are described below.

[55] Kroger-MDL00242231 – 232.

[56] P-KRO-0160 (State of New Mexico, County of Santa Fe First Judicial District Court State of New Mexico, EX Rel., Hector Balderas, Attorney General v. Purdue Pharma L.P.et al, Kroger's Second Supplemental Answers to Plaintiff's First Set of Interrogatories).

Picker and Inspector Manual Review

Levi Brehm, the Kroger 30(b)(6) witness, testified that the Peyton DCs were reviewing orders for appropriateness, but he could not identify the group or a name of a person within the facility that was responsible for the review. He stated that the group had access to controlled substances and had responsibility for reviewing the orders prior to picking them and then notifying DEA of any suspicious order. Brehm was referring to the Inspector review of orders and items picked prior to the order being boxed and shipped. Brehm obtained this information from Peyton employees including Hope Gerber and Jerry Springer.[57]

Hope Gerber was a Pharmacy Second Shift Supervisor at Peyton Northern from 2001 to 2004 and a Pharmacy First Shift Supervisor from 2004 to 2009. During her tenure as the First Shift Supervisor, she described overseeing incoming orders that would be received through the automated computer system SKOPE into her operating system "Chain Store."[58] SKOPE was the acronym for "Standard Kroger Order Processing Environment," an order processing system that sits between the pharmacies and distribution centers.[59]

Gerber testified that the DC received orders in bulk.[60] The orders were broken down by line for the same store.[61] There were one or two pickers in charge of controlled substances on a shift.[62] Once the orders were broken down, the item or items in the order were picked (by an employee known as a "picker") to fulfill a particular order, and the order was subsequently reviewed by an employee/inspector. The job of the Inspector was to *ensure that the items picked for the order were correct, checking the tote with the invoice* and providing a secondary check of the picker's work.[63] The Inspectors (and possibly pickers) would sometimes question odd quantities ordered or anything not normal about the order. When they had questions, Gerber would follow-up with the inventory control department to ensure that the orders were correct. Inventory control would contact the specific pharmacy to clarify how many items they ordered so it could be corrected before it leaves the facility. Their goal was to make sure they were shipping out what they were supposed to be shipping out.[64] It should be noted that an order could be stopped or cancelled through SKOPE, but it appears that this function was not implemented for SOM purposes until 2013.[65]

From 2004 to 2009, Matthew Reisinger was an Assistant Warehouse Operations Manager and Warehouse Operations Manager at Peyton's Phoenix DC. He was employed by a contractor that was managing warehouse behavior for Peyton's Phoenix DC.[66] Reisinger oversaw the employees involved in selecting, packaging and shipping pharmaceuticals.[67] There was no review of individual orders prior to those orders being picked, packed and shipped by Reisinger's department or employees.[68] Reisinger indicated that if the pickers "saw anything out of the ordinary . . . something that doesn't look right, a big quantity," they would have to stop and notify the supervisor.[69] Significantly, Reisinger could not

[57] Brehm Depo., at 315:4-317:5 (Mar. 11, 2021).
[58] Gerber Depo., at 49:17-50:14 (July 20, 2021).
[59] Brehm Depo., at 292:8-16 (Mar. 11, 2021).
[60] Gerber Depo., at 51:3-51:16 (July 20, 2021).
[61] Gerber Depo., at 52:24-53:17 (July 20, 2021).
[62] Gerber Depo., at 54:18-54:2 (July 20, 2021).
[63] Gerber Depo., at 76:20-77:11 (July 20, 2021).
[64] Gerber Depo., at 81:5-85:3 (July 20, 2021).
[65] KrogerSmithNMAG00006922-6925.
[66] Reisinger Depo., at 9:6-10:12 (March 2, 2022).
[67] Reisinger Depo., at 29: 25-30:15, 89:20-25 (March 2, 2022).
[68] Reisinger Depo., at 42:16-45:20 (March 2, 2022).
[69] Reisinger Depo., at 44:3-10 (March 2, 2022).

remember any instance where he was notified of an unusually large order of controlled substances, but he "remembered a lot in other areas of the business."[70]

The Picker and Inspector Manual Review was not an effective component of a suspicious order monitoring system.

The purpose of the Picker and Inspector Manual Review was to determine whether an order is correct and identify potential orders with data entry errors. Therefore, while this mechanism may have identified an ordering anomaly such as an entry order mistake, it is not an effective SOM component that can reliably, objectively, and consistently identify controlled substance orders of unusual size or unusual frequency or that substantially deviate from a normal pattern.

Green and White Bar Monthly Review and "Excessive Purchase" Report

Brehm also described a process, described to him by Hope Gerber and Jerry Springer, where Gerber (when she was stationed at Peyton Northern) would review orders on an order-by-order basis and would compare them to a previous order history. Brehm indicated that if Gerber saw anything that was out of the norm during her review, she would pass that on to Springer, who was an assistant supply chain manager.[71] If that happened, then Springer would contact the pharmacies and make an assessment in conjunction with the procurement team. Brehm said that the final decision whether to fill and ship or cancel the flagged order was made by the procurement team.[72] Although he could not provide specific measures or metrics concerning the appropriateness of an order, nor could he identify any policy or procedure that discusses store size or location, Brehm testified that store size and location were considered as part of this review.[73]

Springer testified that Bob Breetz was his point of contact in the pharmacy procurement department, and that he would call Breetz if they had a question concerning an order, fax him the sheet for excessive orders and procurement would investigate.[74] Springer also indicated that Breetz would contact Springer and tell him to ship or cancel the order no more than one day later.[75] Springer subsequently withdrew his testimony concerning Breetz, stating that Breetz was his contact in procurement but he did not remember speaking with him regularly as part of the process. Furthermore, he did not remember the name of the individuals in procurement that he called regularly as part of the process.[76]

Breetz, however, did not recall being involved in the process at all and advised that it would not be the normal process.[77] Breetz stated that the best that he could recall was that the process would be to deal directly with the regional office or the particular store to investigate the order.[78] In addition to conflicting with Springer's testimony, Breetz's statements conflict with a statement in the Kroger

[70] Reisinger Depo., at 47:9-17 (March 2, 2022).
[71] Brehm Depo., at 348:14-20 (Mar. 11, 2021).
[72] Brehm Depo., at 318:6-319:15 (Mar. 11, 2021); see also Brehm Depo., at 339:10-23 (Mar. 11, 2021) (Gerber pulling off orders from a green bar report to evaluate); Brehm Depo., at 349:20-350:4 (Mar. 11, 2021) (When questioned about who would make the final decision on whether a flagged order is cancelled or filled and shipped to the store, Brehm testified, "Based on testimony from Mr. Springer, that would have been made by the individual he was in contact with at the procurement team").
[73] Brehm Depo., at 326:4-329:12 (Mar. 11, 2021).
[74] Springer Depo., at 49:9-52:3 (July 22, 2021).
[75] Breetz Depo., at 67:19-69:3 (June 28, 2022); Springer Depo., at 51:13-52:3 (July 22, 2021).
[76] J. Springer Deposition Errata (Nov. 15, 2021).
[77] Breetz Depo., at 69:21-70:3 (June 28, 2022).
[78] Breetz Depo., at 70:7-71:20 (June 28, 2022).

Suspicious Order Monitoring 07077 Project Scope, that prior to 2013 Kroger "used our Loss Prevention teams to monitor product movement and investigate suspicious activity, but this was after the product was already shipped to the store and potentially dispensed to customers."[79]

Brehm was describing the Green and White Bar Report reviews conducted by the Pharmacy Shift Supervisor at the distribution centers.[80] However, the details Brehm provided conflicted with the testimony of Gerber, who for example said that this review was done at the end of the month after the products were shipped. In addition, the orders on this report were aggregated over the previous month,[81] so there was no review of individual dates/quantities shipped by item; further, reviewing orders involved one person manually reviewing several months of purchase data to see if there was an increase in ordering. And there were no objective criteria to decide what was "excessive."

Of significance, when asked what suspicious order monitoring program was in place at Peyton Northern between 2004 and 2009, Gerber replied, "So part of it would be the –well, what I was doing on the Green and White bar forms, I guess. I guess I don't know how to articulate. I'm sorry. Part of the monitoring system for what our stores were ordering, so it would be—fall underneath suspicious order monitoring would be the Green and White Bar forms."[82]

Gerber testified regarding the process she followed. She stated that once a month she would receive a Green and White Bar report that was broken down by store, item number, and quantity shipped. The report would list the orders that had been placed and shipped during the previous month.[83] The item numbers in the report were specific to a drug and strength.[84] The report did not contain schedule II products.[85] The report was approximately 4 inches tall [86] and would come from data processing.[87] Gerber maintained 8 to 10 previous months' Green and White Bar Reports for comparison.[88] She would highlight anything that she felt was outside of normal ordering based on the information she had from several months of previous reports. Her training to conduct this task was four weeks of on-the-job training. After this training, because she was a new Pharmacy shift supervisor, her reports were reviewed by the person who provided the on-the-job training.[89] Brehm testified that he did not have any corporate knowledge on training or education provided to Gerber or other employees involved within that role to help identify orders that should be flagged on the report.[90]

There were no objective criteria that Gerber used to determine what should be highlighted.[91] As opposed to any objective criteria or similar guidelines, she stated, "…over time and years doing it, you kind of get a feel for who orders what and when."[92] Gerber testified that she did not calculate average

[79] KrogerSmithNMAG00006475-78.
[80] Brehm Depo., at 339:10-23 (Mar. 11, 2021) (Gerber pulling off orders from a green bar report to evaluate); see also Breetz Depo. 66:8-20 (June 28,2022) (When asked for a description of the SOMS, Breetz responded, "They would review—I think they called it at the time Green Bar reports that they, that they regenerated at various points in time. I don't recall how often, and they would make the determination if an order was excessive").
[81] Gerber Depo., at 132:20-133:11 (July 20, 2021)
[82] Gerber Depo., at 147:2-13 (July 20, 2021).
[83] Gerber Depo., at 102:16-21 (July 20, 2021).
[84] Gerber Depo., at 123:14-124:19 (July 20, 2021).
[85] Gerber Depo., at 113:1-114:5 (July 20, 2021).
[86] Gerber Depo., at 105:11-106:18 (July 20, 2021).
[87] Gerber Depo., at 106:23-107:2 (July 20, 2021).
[88] Gerber Depo., at 121:8-23 (July 20, 2021).
[89] Gerber Depo., at 111:10-112:3 (July 20, 2021).
[90] Brehm Depo., at 348:7-13 (March 11, 2021).
[91] Gerber Depo., at 118:14-119:18 (July 20, 2021).
[92] Gerber Depo., at 109:5-11 (July 20, 2021).

orders (based on the previous 8-10 months), but instead just looked at the normal order quantity. Gerber testified, "No, I didn't calculate the average by adding them all up. So, if—again, if it was normal orders were five to six bottles and this month its five to six bottles, it's within the norm."[93] Gerber also stated that in reviewing these reports, her goal was to ensure they were shipping out orders correctly, to make sure that orders did not change drastically and that they were staying within how the store had ordered in the past. If there was a change, the report that she sent was to make sure someone was investigating why the orders were changing.[94] Gerber estimated that Peyton Northern shipped to over 200 stores.[95]

Once her review was completed, she would send the highlighted copy to her assistant to be typed on a form[96] called the *Excessive Purchase Report.*[97] The *Excessive Purchase Report* had no historical information or explanation as to why an order was included in the report.[98] Gerber delivered the *Excessive Purchase Report* to Springer in his office or placed it in his mailbox.[99] Gerber testified that she did not conduct any investigation into the stores or orders that she flagged for the report. She was not part of any investigation process.[100] She said that there was a process that Springer had to follow once he received the report, but she was not part of that process.[101]

The Green and White Bar Monthly Review and Excessive Purchase Report method fails to identify or stop suspicious orders.

Orders were not blocked pending evaluation and investigation, and I have not been provided with any suspicious order that was reported to DEA when discovered from this system. Gerber's post-shipment review considered only the aggregate compilation of orders for approximately 200 pharmacies. Of significance, Gerber advised that the review was conducted in one shift, indicating that the purchase patterns of at least 200 pharmacies over a 1-month time period were reviewed by an individual who also did an 8- to 10-month lookback for all Schedule III through Schedule V controlled substances, without the benefit of an algorithm or computerized assistance, knowledge of the store location and demographics, and without any guiding objective criteria, in a single day. Armed only with a "feeling" developed through experience and on the job training, the Pharmacy Supervisor identified specific items/orders out of a sea of orders to be placed on an "excessive order" report that was sent for further evaluation. Without the benefit of any justification, factors, or other information that helped Gerber determine why the specific items/orders were selected, Springer was to investigate the stores. Under these circumstances, it would be impossible to identify every order that met the definition of a suspicious order.

Not only is this method ineffective in practice, it was also ineffective as designed. The drug, strength, order frequency, or bottle size were not considered during review. This method could not identify orders of unusual frequency, nor could it identify orders deviating substantially from a normal pattern. By its nature, this flawed method of review only addressed unusual size orders, so for example, if the pharmacy was ordering smaller quantities more frequently or large count bottles (e.g., 500 tablets instead of 100 tablets), these orders would not be identified. In other words, it would not detect small

[93] Gerber Depo., at 129:14-130:8 (July 20, 2021).
[94] Gerber Depo., at 115:8-19 (July 20, 2021).
[95] Gerber Depo., at 55:1-19 (July 20, 2021).
[96] Gerber Depo., at 109:5-100:7 (July 20, 2021).
[97] Gerber Depo., at 160:2-22(July 20, 2021).
[98] Gerber Depo., at 133:12-16 (July 20, 2021).
[99] Gerber Depo., at 134:24-135:3 (July 20, 2021).
[100] Gerber Depo., at 137:8-12 (July 20, 2021).
[101] Gerber Depo., at 137:13-19 (July 20, 2021).

orders (or orders that were not of "unusual size" as determined by the Pharmacy Supervisor's "feeling") even if the order was of unusual frequency or deviated substantially from a normal pattern.

Maximum Order Quantity ("MOQ")

The Kroger 30(b)(6) witness, Levi Brehm, was asked, "Do you have any understanding of any program related to suspicious order monitoring at Kroger or Peyton's that relates to an MOQ or maximum order quantity." In response, Brehm testified, "As it relates to suspicious order monitoring, I do not have any corporate knowledge of that."[102] Brehm was asked, "[I]s it Kroger's position that any maximum order quantity program has anything to do with suspicious order monitoring at Kroger or Peyton." Brehm responded, "I don't have any corporate knowledge on that, Mr. Gaddy to the opinion or basis of the program."[103] However, Hope Gerber testified that "Maximum Order Quantity" is the maximum that a store can order.[104] The MOQ is set by Pharmacy Procurement at Kroger Headquarters.[105] Gerber would not see if the order was cut or not, the maximum she would see on the order would be limited to the MOQ. The MOQ did not affect her because she knew that the orders that she received were at the MOQ or less.[106] Gerber also stated, "We did have max order quantity limits, but, you know, it's on legend drugs and not controlled substances."[107]

On November 12, 2012, Keith Wilson, a Kroger Logistics Regional Controller, emailed Pat Black at Peyton (Corporate) regarding SOM. The email requested that Black provide an explanation concerning the reports that she gets that show the large/unusual movement of controlled drugs that are shipped. Black responded that the first of every month Peyton received a report electronically. The criteria used is in division or store number sequence. Black wrote:

> The criteria we use is if there is one order during the month for any controlled item of 5 pieces or more, all orders for the item for the store are included in the report. The report is reviewed to ensure there are no large quantities of any one item being shipped to any one store. If an excessive purchase amount is noted (and this has never been the case partially based on the order minimums/maximums we have in the system), the Pharmacy Merchandiser for the division of the store in question is immediately notified of the situation for further investigation. While there is no set number of units that is considered excessive, store size and location is also considered in the criteria. This same scenario holds true for OTC product containing pseudoephedrine which we receive on a separate report.[108]

The above explanation appears to be a hybrid of the Green and White Bar Report with the addition of a Maximum Order Quantity (MOQ).

In contrast to the testimony of Brehm and Gerber, in May 2013 (approximately 6 months after the Pat Black explanation email), DEA Diversion Investigator Gary Linder sent a follow-up email to Advantage Logistics Southwest (Peyton Phoenix DC) concerning a DEA Audit follow-up scheduled on

[102] Brehm Depo., at 370:10-20 (Mar. 11, 2021).
[103] Brehm Depo., at 371:5-18 (Mar. 11, 2021).
[104] Gerber Depo., at 96:15-20 (July 20, 2021)
[105] Gerber Depo., at 96:22-98:18 (July 20, 2021); see also, Gerber Depo., at 100:22 – 101:9 (July 20, 2021) (where she stated that she learned of the MOQ from pharmacy procurement but did not know who actually set the MOQ).
[106] Gerber Depo., at 99:3-17 (July 20, 2021).
[107] Gerber Depo., at 82:12-14 (July 20, 2021).
[108] KrogerSmithNMAG00007240.

May 21, 2013. One of the items needed to be discussed in the follow up visit concerned the facility's suspicious order monitoring policy. The email set out three questions that needed to be answered including:

1. If a customer orders more than five units of a controlled substance, do you ship anyway until you receive notice that it was a suspicious order?

2. What if the customer orders 4 units every week, do you still ship and if not, how does the system identify this as suspicious? Does the system identify frequent orders under the threshold as suspicious and if so, how?

3. How long does the off-site order review take (is it real time) and does any delay allow for a suspicious order to go out the first time? The last suspicious order policy you provided stated that your location is contacted at the end of every month regarding suspicious orders. How does this prevent suspicious orders from going out during the month?[109]

In response, Keith Wilson, a Kroger Logistics Regional Controller suggested the following responses:

1. The Kroger RX team has a maximum order quantity on every controlled item (and we will have the MOQ of each item if asked but don't plan on giving it to Gary). If the store orders more than the MOQ, only the MOQ for the Item is shipped.

2. With respect to the first question above, assuming the order for the item is under the MOQ, yes, we ship the item. With respect to the second question, the system does not identify frequent orders under the threshold.

3. Items ordered over the MOQ are automatically held and not shipped. The daily review process may manually reinstate the item ordered if there is good reason – (e.g. as in the case of the mail order "stores" which typically may order larger quantities).[110]

The Kroger corporate response differed from the language suggested by the Advantage Logistics Southwest employee Brent Bilquest. First, in response to question 1, Bilquest suggested that the response also say, "If a store orders more than the MOQ, only the MOQ is shipped and we then review the ordering of the additional items to look for anything that looks suspicious." The corporate response reveals a system where Peyton only ships up to the MOQ and *does not review the amount over the MOQ to look for anything suspicious*.

In response to question 2, Bilquest reported, "currently, we don't have a mechanism in place for this (although the "4 units every week" implies a MOQ of 5 and only ordering once per week). The reality is that an item with an MOQ of 5 could order 4 each order (not each week) and it would not show as suspicious." The corporate response from Wilson admits that the system does not identify unusually frequent orders under MOQ. It fails, however, to report that the orders could be more frequent than

[109] KrogerSmithNMAG00007243; see also Kroger-MDL00236514 – 517 (referencing the supplemental questions posed by DEA from the on-site inspection and how to answer questions concerning the SOM); Kroger-MDL00242235 – 236 (summary of the May 21, 2013 DEA on-site follow-up).
[110] KrogerSmithNMAG00007242-44.

weekly, which could bypass threshold in the aggregate but not by the order. A system that cannot identify orders of unusual frequency violates the provisions of 21§ CFR 1301.74.

In response to question 3, Bilquest suggested that the response contain the statement, "The review of report of all controlled drug ordering is reviewed each period despite the orders having been denied as an extra measure to identify anything suspicious."[111] The corporate response from Wilson omitted this statement. Linder's pointed question zeroed in on Kroger's policy indicating that identified orders were reviewed only after shipment—at the end of each month. Rather than admit that the Excessive Purchase Report was populated by post-shipment Green and White Bar monthly reviews, Kroger responded with information pertaining to the excess MOQ that was not shipped and a "daily review process."

The MOQ process was ineffective at identifying and stopping suspicious orders.

The MOQ was a simple quantity threshold, and it was not an effective mechanism by which to identify or report suspicious orders. Simply cutting controlled substance orders down to an arbitrary threshold (the MOQ) fails to address the concern that these pharmacies were requesting and subsequently dispensing large quantities of highly dangerous and addictive controlled substances. I was not provided with any explanation regarding how the MOQ was calculated for a particular drug item or store, or how it applies to the number of times a week that the item is ordered (frequency) by a particular store. In fact, each pharmacy places 2-3 orders per week, with approximately 75% of the pharmacies placing 3 orders per week.[112]

The MOQ system was also deficient because it failed to account for the fact that each pharmacy can place daily orders from Cardinal for Monday through Friday deliveries to obtain drugs that are on back order, out of stock, and for items needed more quickly than the next Peyton DC order/delivery.[113] The unrestricted and unmonitored use of secondary distributors allows pharmacies to circumvent the MOQ and avoid identification of orders as suspicious. This is similar to the procurement of CII products from Cardinal as explained by Bob Breetz. Breetz explained that Kroger pharmacies ordered CII products directly from Cardinal. Kroger was provided with various reports on a timely basis as it relates to overall company purchases of a given product. However, if a particular store ordered an excessive amount of a CII product from Cardinal, Breetz testified that nobody at Kroger would know about the excessive CII purchases until Cardinal reported to Kroger that a specific store order was being held.[114] This is also supported in a Kroger FAQ document dated October 9, 2013 that states, "Currently, each wholesaler's SOM algorithm/program operates independently, as the DEA's requirement for SOM is on the wholesaler. However, upon a store's order being identified as an order of interest, the LPA team will perform an analysis of Cardinal purchases. In the future, Kroger will perform a complete analysis of purchases from both sources. While there is not currently a system in place to prevent a pharmacy from ordering pended items from Cardinal, pharmacies and Pharmacy Coordinators are to be reminded of the importance of identifying the underlying cause for the original pended order of interest, and determining its appropriateness."[115]

Without providing employees who are responsible for reviewing orders at the DC level with basic information concerning methodology as simple as how an MOQ is calculated, what is considered normal or abnormal ordering frequency patterns, or determining what constitutes a substantial deviation from a normal pattern, suspicious order identification will be difficult to impossible. Without employees

[111] KrogerSmithNMAG00007242-44.
[112] KrogerSmithNMAG00007981.
[113] KrogerSmithNMAG00007981.
[114] Breetz Depo., at 58:9–59:11 (June 28, 2022).
[115] KrogerMDL00011086-098, at KrogerMDL00011090; see also Loesch Depo., at 329:6–332:9 (July 7, 2022).

knowing what the item purchase limits were and how they were calculated, there could be no consistent review of orders flowing through the system.

This type of oversight/review of orders does not help the distributor determine why a pharmacy is ordering large quantities, nor does it trigger a due diligence analysis that would try to determine if the pharmacy is conducting corresponding responsibility on incoming controlled substance prescriptions or whether the substances are otherwise destined for diversion. Cutting the order to the MOQ, if the MOQ is the standard and trigger for due diligence and is the basis of the SOM program, does not resolve the suspicious nature of the order nor does it relieve Kroger of the legal responsibility to notify DEA when a suspicious order is discovered. It also does not relieve Kroger of the duty to maintain effective controls against diversion and not to ship the order unless the suspicion is resolved.

Large quantities of controlled substances, especially high dose, single entity and combination opioid products, should be reviewed and questioned at not only the DC by the Pharmacy Supervisors, but at Kroger Headquarters by whatever section oversees pharmacy operations/compliance since they should understand why these products, ordered in large quantities, are suspicious or not. If they ship up to a pre-determined limit and hold the remaining drug pending review or simply cancel the remaining order, they never get to answer why the pharmacy was ordering the quantities that it did and never dispel the suspicion associated with the order. Meanwhile, if there are suspect prescriptions being filled at the pharmacy, they continue to get filled in competition with legitimate prescriptions that are also presented for dispensing. Under the Kroger MOQ process, suspicious orders are missed, due diligence obligations are ignored, and the true nature of suspicious orders is never determined. Therefore, shipping the orders up to a certain quantity and holding or pending the remaining quantities, or cancelling a portion of the order, without establishing if the order is truly suspicious violates the registrant's requirement to maintain effective controls against diversion.

The Kroger Pharmacy Role in Identifying and Reporting Suspicious Orders

The Kroger corporate witness, Levi Brehm, could not identify any policies and procedures that were specifically related to Peyton DCs' SOM programs, including suspicious order identification, due diligence, prevention of order shipment and DEA reporting, stating that they were unable to locate those documents due to the passage of time.[116] During repeated questioning about pre-2013 documents, he would neither confirm nor deny the existence of Peyton policies and procedures prior to the establishment of a formal, statistical threshold-based SOMS in 2013.[117] Likewise, I was not provided with any specific policies or procedures related to Peyton's suspicious order monitoring policies and procedures prior to implementation of the statistical system in 2013. Indeed, I could not locate any specific document in the 2006 to 2012 time period that mentions "suspicious order." Notably, Jeff Loesch, one of the employees involved in the development /implementation of the electronic SOM program in 2013, could not explain what SOM program was or was not in place prior to 2013.[118]

Brehm referenced the Kroger Pharmacy Controlled Substance Standard Operating Procedure V.2.[119] This operating manual stated, "The following operating procedures were written to provide a single source of current information for ***Kroger Company Pharmacies*** regarding Drug Enforcement Administration (DEA) policies and the requirements of the Comprehensive Drug Abuse Prevention Act (Public Law 91-5132), otherwise known as the Controlled Substances Act of 1970 or the CSA and

[116] Brehm Depo., at 301:1-302:8 (Mar. 11, 2021).
[117] Brehm Depo., at 303:4-308:4 (Mar. 11, 2021).
[118] Loesch Depo., at 172:22–173:19 (July 7, 2022).
[119] KrogerSmithNMAG00002122.

Implementing regulations."[120] My review shows that this manual is focused on Kroger Pharmacy procedures, rather than Peyton distribution centers, the entity that is responsible for identifying, evaluating, reporting and preventing the shipment of suspicious orders. In recognition of this important distinction, Brehm testified that these policies did not directly apply to distribution centers but indicated that they "…still describe some activities that were occurring.[121] He did not identify this as the Kroger or Peyton SOM program.

The pharmacy manual contains SOP #22, *Excessive Purchases and Fraudulent Prescriptions*, dated May 1, 2006, which states in relevant part:

> Responsibility: The Division Merchandisers/Directors of Pharmacy have a broad responsibility to provide leadership and assure the standards established in this SOP are adhered to by pharmacists in their divisions. The Pharmacy Specialist/Coordinator is responsible for exercising due diligence in evaluating excessive purchase information.
>
> Excessive purchase information: Excessive purchase information regarding individual pharmacies received from Peyton or other sources will be forwarded to the Pharmacy Specialist/Coordinator. The Pharmacy Specialist/Coordinator will initially evaluate the nature of the information to determine whether it may be an indication of diversion or whether pharmacy purchasing requirements reflect explainable business or practice conditions (i.e. a pharmacy close to an oncology practice may fill a large number of prescriptions for pain medications, including controlled medications). If the Pharmacy Specialist/Coordinator determines that the excessive purchases are an indication of possible diversion, the Specialist/Coordinator will alert the Division Merchandiser/Director of Pharmacy to initiate an internal investigation. If the excessive purchase information can be explained, a report should be prepared by the Specialist/Coordinator and filed in the folder Notes, Records and or Findings as noted in SOP #2.[122]

It should be noted that the Pharmacy Specialist/Coordinator and the Division Merchandiser/Director of Pharmacy are *pharmacy* employees rather than *distribution center* employees.[123] The above policy is likely related to the Green and White bar monthly review because it populates the "Excessive Purchase Report" and is ultimately passed to pharmacy operations. However, the Excessive Purchase Report is transmitted after a review is completed of the Green and White Bar report and certain stores/orders are flagged.[124] As previously discussed, this is insufficient to meet the distributor's obligation to identify and stop suspicious orders and also fails to control against diversion. There is nothing in this policy to explain what criteria, procedures, or metrics the pharmacy employees should use to evaluate the information; or how any information about suspicious orders would be reported to DEA, if at all.

The pharmacy manual also contains SOP #4, *Ordering Controlled Substances*, dated May 1, 2006, which states in pertinent part:

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[120] KrogerSmithNMAG00002123 (emphasis added).
[121] Brehm Depo., at 311:13-312:20 (Mar. 11, 2021).
[122] KrogerSmithNMAG00002190-91.
[123] Brehm Depo., at 334:6-21 (Mar. 11, 2021).
[124] Gerber Depo., at 160:2-20 (July 20, 2021).

> Responsibility: The Pharmacy Manager has responsibility for ensuring compliance with this procedure.
>
> Procedure - Schedule III, IV and V Controlled Substances: Schedule III, IV and V controlled substances will be ordered from Peyton or another DEA registered supplier. Orders that are placed with Peyton will be automatically generated by the computer assisted ordering system and reviewed for appropriateness. Orders that are placed with other DEA registered suppliers will be made in conjunction with procedures required by the suppliers. Any unusual orders should be reviewed by the Pharmacy Manager before releasing the order.[125]

This policy is about ordering controlled substances, reviewing those orders for "appropriateness," and reviewing "unusual orders" before release. Yet there is no guidance pertaining to what is "appropriate" or "unusual," nor is there any mention of suspicion, unusual size, unusual frequency, or substantial deviation from a normal pattern. Matthew Jensen, a long-time pharmacy manager and pharmacy district coordinator, did not know what Kroger's SOM policy was prior to 2013, other than knowing that they had programs to monitor. He was not privy to that information. He also couldn't remember seeing any SOM SOPs from Kroger or any procedures to identify the investigative process or the process to clear orders.[126]

The above policies discuss "excessive purchases," "appropriateness," and "unusual orders." Neither of these SOPs discuss suspicious orders or otherwise describe the policies and procedures or any other specific information to guide employees through the process of evaluating orders for suspicion as defined by regulation. Even if these policies were genuinely part of a SOM program, the fact remains that orders from the MOQ and the Green and White Bar/Excessive Order Report were shipped before any evaluation of the orders. More important, the above policies were aimed at the *pharmacies*' activities, rather than the distribution centers' activities. Specifically, Kroger required the pharmacies to exercise due diligence in evaluating their own "excessive purchase" information and to review computer-generated orders for "appropriateness;" and Kroger gave authority to the pharmacy to release "any unusual orders" upon review. Needless to say, this creates an environment ripe for self-dealing. In essence, these Kroger policies allow the fox to guard the henhouse by instructing the pharmacies that could place potentially suspicious orders to simply monitor themselves and decide for themselves whether their orders should be filled. This utterly fails as an effective mechanism by which to identify and report suspicious orders and it is not what the closed system of distribution requires of registrants.

Period 2: 2013-2014

Statistical Threshold-Based System: The "Buzzeo System"

In approximately December 2012, Kroger's counsel began discussions with Buzzeo PDMA (subsequently known as Cegedim-Dendrite and collectively referred to herein as "CDM") to assess and provide consulting services regarding the Kroger Suspicious Order Monitoring System.[127] Internal email correspondence in February 2013 confirmed that Kroger was considering a Buzzeo solution/SOM proposal. In response to concerns regarding internal/external cost for the project and whether Kroger internal systems had the required capabilities, Kroger Director of Pharmacy Mark Woolf commented that he understood these concerns but Kroger was "… living on borrowed time on this issue." This

[125] KrogerSmithNMAG00002134-35.
[126] Jensen Depo., at 124:7–126:8 (June 20, 2022).
[127] Kroger-MDL00155649.

assessment was confirmed by Kroger's counsel's office who wrote, "As Mark said, we are on borrowed time from regulatory standpoint."[128]

In March 2013, CDM provided Kroger with an initial written assessment of Kroger's compliance with the provisions of 21 CFR 1301.74(b), ultimately concluding that Kroger did not have a suspicious order monitoring system that was compliant with the regulations and the DEA policy letters issued in 2006 and 2007, the standard operating procedures for the distribution centers did not contain any information pertaining to suspicious order monitoring, and the distribution center managers "… had no firm knowledge or awareness of the firm's suspicious order monitoring responsibilities."[129]

This report was provided pursuant to a Customer Service Agreement signed by Kroger on January 24, 2013 whereby CDM would review, comment and provide consulting recommendations to help strengthen Kroger's SOM and due diligence program. CDM employees also visited Kroger pharmacies and distribution facilities as part of this assessment.

CDM reported deficiencies chiefly in Kroger's reporting, due diligence activities, and training. First, the excessive purchase reports submitted on a monthly basis were historical and not used in practice. In fact, one employee stated that in 20 years she noted approximately five suspicious orders for review and interviews with staff failed to disclose any instance when an order was reported to DEA.

In addition, Kroger did not conduct due diligence investigations on new or prospective customers; did not have an electronic order entry system to analyze orders in real time to determine whether the order may be suspicious; did not have standard operating procedures related to distribution and inadequate SOPs related to pharmacies/pharmacists; and did not furnish adequate corporate training for controlled substance abuse in the context of suspicious order monitoring. Of significance, Kroger pharmacists were not fully familiar with the term and meaning of corresponding responsibility.

Finally, the CDM report recommended that Kroger launch an internal training/SOM awareness initiative immediately, stating "Rudimentary SOM procedures should be established and communicated to affected personnel through a corporate guidance document."[130] In a subsequent report concerning Kroger (Peyton) distribution center employee interviews, CDM concluded that Kroger staff had some general knowledge of excessive purchases but there was no program or system in place to analyze orders and report suspicious orders to the DEA as required by the regulations. Furthermore, the distribution SOPs did not contain any information pertaining to suspicious order monitoring and distribution center managers had "… no firm knowledge or awareness of the firm's suspicious order monitoring responsibilities."[131]

Internally, Kroger was aware that they were not in compliance with the regulations. Kroger employee Laura Rainey was answering pseudoephedrine certification documents for the Perrigo company. As part of this process, in November 2012 Kroger was asked questions about their SOM. In February 2013, Kroger had still not answered the questions. In March 2013, Rainey sent an internal email to Kroger employees explaining that she would answer Perrigo by stating "… Peyton is in the process of implementing a Suspicious Order Monitoring Process." She also wrote, "Because we do not have a SOM process in place at this time, there is a good chance they will stop shipping us product."[132]

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[128] Kroger-MDL00156164 -168.
[129] Kroger-MDL00061701.001-701.006.
[130] Kroger-MDL00061698- 699.009.
[131] Kroger-MDL00061700.001; Kroger-MDL00061701; Kroger-MDL00061701.001-1701.006.
[132] Kroger-MDL00137511 – 513.

Pursuant to CDM's assessment, Kroger continued internal meetings to develop a SOM program. In an April 5, 2013 email from Keith Wilson, a Logistics Regional Controller, to several Kroger employees, he explained that the key to the program "… is to have a method of reviewing orders BEFORE they are processed and shipped to the stores." This email referenced on-going discussions with CDM and the use of a CDM developed algorithm that would either be incorporated into the Kroger system or would send the information to CDM to have the work done in a cloud-based environment. The email also discussed and described the different portions of the system that must be developed.[133]

In May 2013, Kroger continued to have internal meetings to discuss SOM. Based upon the documents provided, it appears that a meeting occurred on May 21, 2013,[134] the same day that DEA was scheduled to meet with employees at Peyton Phoenix to follow-up an earlier DEA on-site inspection.[135] Prior to the meeting with Peyton Phoenix, DEA Diversion Investigator Gary Linder requested that facility management provide answers to specific questions related to the on-site inspection to include questions regarding the SOM program employed by the facility. These questions and subsequent answers were discussed earlier in this report in the MOQ section.

In June 2013, Kroger was *still* trying to develop a short-term solution to the SOM while the algorithms were being developed and deployed.[136] Sometime around July 2013, Kroger contracted with CDM to develop a SOM system for the distribution of controlled substances. CDM was brought in to create a system designed to ensure that the Kroger controlled substance ordering process complied with regulatory guidance and DEA guidance that included the three guidance letters sent to all manufacturers and distributors in 2006 and 2007, including Peyton DCs.[137]

On July 13, 2013, CDM provided Kroger with a Descriptive Overview Document that explained their proposed SOM Model.[138] Essentially, this SOM process is a statistical threshold-based system. The system recommended by CDM was designed to "pend" or stop an order from being shipped if it was classified as "suspicious" and potentially reportable. The system was designed to evaluate orders and determine whether they fit into DEA's definition of suspicious orders. This was done by assigning a score to each product line item based on attributes (order qualities) and variables that represent characteristics of the order with the attributes based on a 12-month historical database. The system determines whether an order contains factors that would be associated with a suspicious order and assigns a numerical value to each factor based on the significance of the factor (weighted values). An order with high weighted values may be considered suspicious and "pended" for further evaluation to determine if it is a suspicious order for reporting purposes. The CDM SOM identified any order with a score of 0.15 or higher as potentially suspicious and "pended" the order, thereby triggering further evaluation of the order.[139] The potentially suspicious order was identified as an "order of interest."[140] The cumulative amount of active ingredient ordered by a particular customer for the current month is the common

[133] Kroger-MDL00227022-7024.
[134] KrogerSmithNMAG00008253.
[135] KrogerSmithNMAG00007243. Peyton Phoenix did not distribute to any Kroger pharmacies in Cobb County, Georgia, during the relevant ARCOS reporting period.
[136] Kroger-MDL00243083 – 087.
[137] Kroger-MDL00061701 (CDM audit report referring to "the regulations and DEA's policy letters issued in 2006 and 2007," including specifically the December 27, 2007 letter); see KrogerSmithNMAG00003203 (copy of the December 27, 2007 letter to Peyton Northern, Bluffton Indiana).
[138] KrogerSmithNMAG00006760.
[139] KrogerSmithNMAG00002579-80.
[140] KrogerSmithNMAG00004605.

measurement used in the CDM SOM model and is evaluated against the attributes that are functions of the history fields (ordering history).[141]

Kroger established a short-term and long-term approach to implementing the proposed SOM project. The short-term solution was to establish a manual system to conduct SOM monitoring. This was a "quick and simple solution" to bridge the gap until a long term solution could be put in place.[142] It was necessary because, "Kroger is out of compliance for SOM until we have a valid process and audit data available."[143] An August 5, 2013 update stated, "This project will be delivered in a single phase: we will follow normal software release cycle accompanied by the appropriate training."[144] An August 9, 2013 update added an assumptions/constraint section that indicated suspicious order details need to be kept for two years; the Buzzeo Algorithm will live in SKOPE and will be applied when orders are processed; the algorithm will evaluate the ingredients of an item when the orders are processed; and the Loss Prevention/Asset Protection ("LPA")team will document orders of interest and Suspicious Orders investigation details in the LPMS application.[145]

On September 30, 2013,[146] more than five years after the 2007 DEA letter was sent to distributors, CDM/Kroger finally deployed and integrated the SOM model (also referred to as the "Buzzeo System") into their ordering system and began implementation of the new process at the Bluffton Distribution Center (i.e., Peyton Northern). The system was initially set to pend orders with a score of 0.15.

Orders of Interest Process

Once the Buzzeo System was implemented, it was placed in line with the SKOPE system. After entering SKOPE, the Buzzeo System would evaluate the controlled substance orders using the criteria described above. If an order was identified as an order of interest, the Buzzeo System flagged the order and changed it to a hold status, preventing it from being submitted to the DC for fulfillment. The order of interest report was then sent to the LPA Team.[147] The report included:

- All orders pended;
- List of items in order of interest;
- Reason flagged;
- List of active ingredients flagged for order items;
- Pharmacy shipment history for flagged order items; and
- Cancelled order details[148]

[141] KrogerSmithNMAG00002580. It's not clear from the materials whether the CDM algorithm incorporates analysis of specific high abuse dosage forms of a particular class of drugs as necessitated by drug trends, or it accounts for cumulative active ingredient only. This is a potential weakness in the algorithm.
[142] KrogerSmithNMAG00006765.
[143] KrogerSmithNMAG00006763.
[144] KrogerSmithNMAG00006761.
[145] KrogerSmithNMAG00006477.
[146] KrogerSmithNMAG00006858; see also Kroger-MDL00225649.
[147] KrogerSmithNMAG00004614; KrogerSmithNMAG00000858 (The report is sent to the Loss Prevention Management System (LPMS)).
[148] KrogerSmithNMAG00004614.

The order of interest report was then reviewed by a MAX/LPA Team.[149] The LPA will attempt to clear orders using available background information on the pharmacy and order. The LPA reviewed the report information, pharmacy order history with drug, notes in the pharmacy file pertaining to the drug, whether other orders for the account have been pended before and what actions were taken previously. The LPA also obtained a list of previous orders of interest and suspicious orders.[150] The potential reasons for clearing an order include: order error, purchasing early before holiday closings, new customers, new or different drug, or different dispensing/product size.[151] Only the LPA can clear a pended order, and only after appropriate investigation.[152] The SOM SharePoint database is used to input exceptions that would otherwise flag an order as an order of interest. It is used to potentially clear orders of interest, and input is restricted to Corporate Pharmacy, Divisions (Merchandisers and Coordinators) and Loss Prevention.[153]

If the order was cleared, the order status would be changed to open status and the order was sent to the DC for fulfillment. If the order could not be cleared, LPA contacts the Prescription Coordinator ("RXC") for additional investigation. Peyton Logistics is also notified. The RXC performs review of ordering/dispensing habits, reviews recent dispensing for red flags,[154] and ensures pharmacists are exercising corresponding responsibility.[155] Results of interviews with coordinators are documented.[156]

If further investigation by the RX Coordinator could not clear the order, the order was flagged as suspicious, and the Corporate Pharmacy and the Division Merchandiser were notified. Peyton Logistics was also notified, and they notified DEA of the suspicious order.[157] If orders cannot be cleared of suspicion or if the pharmacy has previous orders pended and provided similar reasons, the reasons will be investigated further, and the Division Pharmacy Merchandiser will be contacted.[158]

Audit Program

There was also an Internal Audit Program that requires pharmacies that have had three pended orders of interest within a period to complete the Pharmacy Survey[159] and return it to LPA for review.

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[149] KrogerSmithNMAG00000888. In the 2013 suspicious order monitoring training manual, the program policy and procedure section stated, "Responsibility – While overall responsibility for the operation of the Suspicious Order Monitoring Program belongs to the Peyton Regional Distribution Centers, Pharmacy Loss Prevention Associates will research, evaluate and release Orders as well as determine whether an Order is suspicious on behalf of the Peyton Regional Distribution Centers. Each Peyton Regional Distribution Center will handle reporting Suspicious Orders to the DEA and/or state regulatory agencies, as more specifically set forth herein."
[150] KrogerSmithNMAG00004614-15.
[151] KrogerSmithNMAG00004620.
[152] KrogerSmithNMAG00004627.
[153] KrogerSmithNMAG00004621.
[154] KrogerSmithNMAG00004618 (Red flags are indicators that a prescription may not be legitimate. Kroger identified the red flags as cash, out of state patients, lack of physician qualifications, large percentage of CS vs. NCS, lack of patient contracts, lack of alternative treatments, DEA compliance issues, lines of patients, suspicious activities, guards and paying cash prior to entering office.).
[155] KrogerSmithNMAG00004617. In contrast, see Kroger-MDL00034865 ("Within the area of DEA compliance, our areas of highest risk include (1) our pharmacists' inconsistent and often absent understanding of DEA's expectations for executing proper corresponding responsibility related to the dispensing of controlled substances…").
[156] KrogerSmithNMAG00004619.
[157] KrogerSmithNMAG00004610; KrogerSmithNMAG00002092-2121 (copies of notifications of suspicious orders sent to DEA (2014-2019)).
[158] KrogerSmithNMAG00004629.
[159] KrogerSmithNMAG00000941-945 and KrogerSmithNMAG00000935-938.

LPA will contact the Division Merchandiser if Pharmacies have five pended orders of interest within two consecutive periods. The Merchandiser will oversee a professional audit of the pharmacy.[160]

Documented DC Responsibilities

A December 2013 PowerPoint titled "*Suspicious Order Monitoring Update and Pre Holiday Discussion*" explained the program elements and responsibilities of specific Kroger entities. The slide titled "SOM Overview/Program Elements" reflected the following elements:

- Appropriate due diligence and "know your customer" activities – determine the legitimacy of existing and potential new customers (pharmacies)'
- SOM Model – identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency (statistical based model);
- Appropriate review and/or investigation of pended orders;
- SOM SOPs – Procedures to identify investigative process, process to clear orders, DEA reporting, closing accounts, etc.;
- Training-Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse.[161]

The slide titled "Peyton's SOM Responsibilities" indicated the following:

- Peyton: Overall responsibility for operation of the SOM; reporting suspicious orders to the DEA;
- LPA team: Conduct investigations, evaluate orders, release orders, determine whether an order is suspicious;
- Legal & Corp RX Regulatory and Compliance: Provide guidance to LPA & divisions;
- RX Coordinators: Additional research on request from LPA[162]

This document, as well as the previously discussed documents released in 2013 related to the development and deployment of the Buzzeo System, were the earliest written directives that I reviewed of any viable SOM utilized by Kroger/Peyton DCs during the 2006 to 2014 review period, and the earliest allocation and description of duties related to the operation of the Kroger SOM.

Min/Max Ordering

The December 2013 PowerPoint also discussed "Min/Max Findings," stating: "Majority of pharmacies with pended orders had adjusted min/max upward manually."[163] Brehm testified that

[160] KrogerSmithNMAG00004632.
[161] KrogerSmithNMAG00006483.
[162] KrogerSmithNMAG00006484.
[163] KrogerSmithNMAG00006489; see also KrogerSmithNMAG00007982 (Pharmacies have the ability to override Min/MAX as needed.).

Min/Max Quantities were order point adjustments being conducted by someone within the pharmacy, increasing that based off what was already set within the system. And there's any number of valid reasons why that could be."[164]

This process was explained in a separate PowerPoint given to the CDM team in April 2014. Under the title "Ordering Logic," all controls and prescription monitored items are ordered in the EPRN pharmacy system and a suggested order is generated based on min/max logic. The pharmacy performs a quick review of order before it is transmitted, and pharmacies have the ability to override min/max as needed. EPRN and CAO orders are sent to SKOPE and have the same Peyton order number. The order is broken down in SKOPE to monitored RX items, pseudoephedrine items and others.[165]

Based on these documents, it appears that the pharmacy could adjust the Min/Max quantities using a Temporarily Control Min/Max command. This adjustment could be made after taking into consideration the amount that is being dispensed and potential new business. The pharmacy was cautioned not to overestimate the minimum since they receive Peyton orders every few days and keeping 6 to 7 days' worth of supply in stock may not make sense. The pharmacy was further cautioned that adjusting the Min/Max quantities on controlled substances could trigger an audit or have SOM implications, potentially impacting service to the customer.[166] Brehm was asked, "But regardless, at least in 2013 when the software would suggest an order quantity, the store had the ability to raise, I would imagine also lower, that quantity if they felt that was appropriate for their store, correct?" Brehm answered, "Based on this document."[167]

This document also stated that the SOM SharePoint Database was "[n]ot being consistently utilized by divisions."[168] Brehm testified that he had no corporate knowledge of why it was not being utilized consistently by the divisions.[169]

Investigation of Orders/Due Diligence: Training

According to the December 2013 PowerPoint presentation, training is an element of the Kroger SOM. Training was described as "Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse."[170] In 2013, Kroger created a training manual for suspicious order monitoring for Loss Prevention and Asset Protection.[171] The manual provided a step-by-step method for reviewing orders that have pended with examples how to search different data sets within and outside of the LPMS. This system appeared to be mechanical and assumes that most orders can be cleared by looking at previous purchase patterns or ordered items, pends/clearances, and balance on hand.[172] If the order could not be cleared through SKOPE, the review moves on to business objects such as BzO (dispensing variances), Min/Max, and 30-day and 100-day movement.[173] Notes in the customer file pertaining to the pended drug and what previous actions were taken on these orders are also reviewed.[174]

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[164] Brehm Depo., at 224:10-225:1 (Mar. 11, 2021).
[165] KrogerSmithNMAG00007982.
[166] KrogerSmithNMAG00006490.
[167] Brehm Depo., at 226:15-21 (Mar. 11, 2021).
[168] KrogerSmithNMAG00006492.
[169] Brehm Depo., at 227:9-13 (Mar. 11, 2021).
[170] KrogerSmithNMAG00006483.
[171] KrogerSmithNMAG00000856-897; KrogerSmithNMAG00000898-934.
[172] KrogerSmithNMAG00006483.
[173] KrogerSmithNMAG00000911-915.
[174] KrogerSmithNMAG00000932.

The manual stated, "In most cases, an order can be cleared using the information listed above. However, in the case where an order cannot be cleared, the next step is to contact the pharmacy coordinator and conduct further research."[175] The manual also has instruction on how to use SKOPE in place of the SOM web application when it is not available or when there is a system outage.[176] This document also contained the SOM policies and Procedures for Peyton DCs that included an overview of the review process and reporting procedures.[177]

This training manual did not get into the nuts and bolts of how to objectively evaluate and analyze the available information to determine whether to clear the order or continue to investigate. It fails to explain what the pharmacy coordinator must review and how he/she should use this information to decide whether the order should be cleared.

There is also a training manual titled, "Suspicious Order Monitoring Training Manual" that provides detail regarding delegation of responsibilities but little information on how to actually perform due diligence. Under the title of additional resources, it states, "SOM analyst will view SOM SharePoint for announcements on that location posted by the division." It then cites examples such as pain clinic open nearby; neighboring pharmacy closed, file purchases, Parata Max Installation.[178] This provides little guidance on how the pharmacy coordinator should perform due diligence activities or evaluate relevant information. Compounding the problem is that the examples given are not necessarily good reasons for clearing an order. These circumstances (pain clinic open nearby, neighboring pharmacy closed, file purchases) may also be a reason to stop or cancel orders from being shipped, and as such require a deeper inquiry. Some "pain clinics" are "pill mills" and prescribe large quantities of controlled substances illegally; pharmacies involved in diversion close and sell their prescription files, providing false validation of suspect prescriptions/patients to the pharmacy that purchased the files. These circumstances open another avenue of investigation rather than provide a reason for order clearance. This ambiguity makes it even more important that detailed guidance on how to analyze and evaluate the information be provided to those charged with due diligence responsibilities.

The Pharmacy Coordinator has a crucial role in this process. The LPA employees are investigators, but there is no information to suggest that they are pharmacists and have the knowledge and experience to qualify them to review dispensing activities. Therefore, the review that the LPA performs is more related to volume and historical ordering patterns—generally a mechanical process. These reviews are important, but of equal or greater importance is what happens to the drugs at the pharmacy level and whether the pharmacist is conducting an appropriate corresponding responsibility analysis or just filling every prescription that comes through the door regardless of red flags. The review of prescription dispensing and analysis, drug choice, and drug-to-treatment comparison can only be done by a professional who understands the science of drug therapy (e.g., a pharmacist). For that reason, the Kroger SOM process should involve a pharmacy coordinator (or someone equally qualified) and should include detailed training on how to conduct these reviews to objectively determine if the suspicion can be dispelled or not. It is my opinion that there should be more detail in the education and training of the

[175] KrogerSmithNMAG00000901-910.
[176] KrogerSmithNMAG00000919-929.
[177] KrogerSmithNMAG00000929-934; see also KrogerSmithNMAG00007232-7233 and KrogerSmithNMAG00007230-7231 (concerning communications procedures).
[178] KrogerSmithNMAG00000858; see also KrogerSmithNMAG00007195 (a document that appears to be the prelude to the SOM Workflow – Overview titled Future LPA Process Flow with SOM – 7/5/2013 that explains the Pharmacy Coordinators role and duties in the evaluation process. The document states that if the LPA cannot initially clear the pended order, the RX Coordinator will be contacted and he/she will research the store for any verification of order to include pain clinic nearby, neighboring pharmacy nearby closed, seasonal sales swings. As explained in the body of the report, some of these could be considered red flags. Seasonal sales swings are most likely associated with pseudoephedrine which is not part of this litigation.).

LPA and Pharmacy Coordinators to ensure consistent, informed, and reasonable decisions are made in the clearance/resolution process.

Investigation of Orders/Due Diligence: Use and Evaluation of Historical Information

All of the training in the world on performing due diligence will be useless if there is no historical information necessary to perform the investigation. One of the basic elements of the SOM process is due diligence and know your customer activities that will help determine the legitimacy of existing and potential new customers.[179] One way of accomplishing this is through a pharmacy survey that lists questions concerning specific characteristics that could indicate that the pharmacy was not following State or Federal law, as described throughout this report, and specifically information about the customer in the "Closed System of Distribution" section above. The survey becomes a foundation or baseline of information that could be referenced when determining the legitimacy of an order or anomaly in ordering pattern. For self-distributing pharmacies, obtaining this type of information should be a comparatively simple matter. In 2013, Kroger developed a survey to help determine the legitimacy of its pharmacy customers.[180] When questioned whether an existing Kroger or affiliated pharmacy received this survey prior to September 2013, Brehm testified that he had no corporate knowledge, adding that Kroger's typical document retention policy is two years, so he didn't have any corporate knowledge of any pharmacies filling out the survey.[181]

It would be irrational to dispose of a record or other information that is critical to the success of a SOM program – establishing baseline customer information that will assist in determining legitimacy of orders. If the employees that are investigating orders do not have this information, they are deprived of potentially crucial information in determining the legitimacy of orders (and customers) and their job will be more difficult when trying to establish a shift in ordering pattern, especially when looking back to when the customer started ordering. The system should not just identify patterns within the current month, but also historical patterns that show threshold "creep" with no justifiable reason. It doesn't matter how long ago the report was completed or the information obtained, so long as there is a historical perspective of ordering history to make a comparison that puts a potential suspicious order into perspective.

As a self-distributing pharmacy, Kroger has access to their own pharmacies' ordering and dispensing history irrespective of how long ago the ordering or dispensing occurred, without the use of a special form. Especially for self-distributing pharmacies, those conducting due diligence would reasonably be expected to obtain their own pharmacies' information such as historical ordering and dispensing patterns, customer base, local demographics, etc. to inform the due diligence evaluation. If the relevant historical and customer information is collected on a form and maintained for the duration of the distributor-pharmacy relationship, order evaluation would be streamlined and efficient. If that information is not collected or otherwise maintained, the person conducting due diligence would still be expected to collect that information from available resources and evaluate it in the context of dispelling suspicion surrounding an order.

Drastic Adjustments to the Statistical Threshold

In September 2013, Kroger was preparing to deploy the Buzzeo System. On September 17, 2013, an email was sent to a CDM associate inquiring about the use of inflated order volumes to establish a historic baseline for a particular pharmacy and how it would affect the SOM. Kroger asked, "if there

[179] KrogerSmithNMAG00004602.
[180] KrogerSmithNMAG00000935-938; see also KrogerSmithNMAG00000941-945.
[181] Brehm Depo., at 185:2-191:21 (Mar. 11, 2021).

were a circumstance under which a particular location's monitored item order volume has been inflated throughout the past year (presumably due to fraudulent or reckless behavior) and for whatever reason, is currently not under any suspicion, then have we in essence established a baseline of activity that would not be identified by the algorithm as suspiciously high going forward? Or are there some absolute levels of activity that would alert us to this situation?" A CDM associate responded that Kroger's concerns were valid, saying "essentially the algorithm is only one part of your SOM program. Your SOPs are critical to making sure that your stores ordering is appropriate. You are correct in saying that if the history reflects fraudulent behavior, then the model will not detect ongoing fraudulent behavior."[182]

This response should have generated serious concern at Kroger. Kroger really had no compliant SOM program until it instituted the Buzzeo System, and they had no real data or information regarding their pharmacies' ordering patterns. Therefore, it was a real possibility that inflated numbers from 2006 to 2013 were being used as a baseline in the Buzzeo System, because the system was programmed to assume that the past ordering data did not include any orders that were suspicious, but in fact it is likely that they did include suspicious orders—especially in light of the lack of a compliant SOM system for that entire period of time.

Kroger conducted a trial run of production orders prior to deploying the Buzzeo System and discovered a pend rate of 76%, meaning 76% of orders were at or above the 0.15 statistical threshold. This was reported to CDM on September 27, 2013, with a plea: "We are in dire need of understanding why we are seeing such an inflated number and are hoping you can let us know when you may be available to give us some direction."[183] In response, a CDM associate revised the DateEffect component of the system.[184]

In correspondence dated September 30, 2013, Dustin Tumblison advised the CDM team of a 28% pend rate on September 28th, and stated, "We are going live today [September 30] with the SOM algorithm but need to understand why we are still getting such a high pend rate. The business team, if the percentage rate holds, will need to investigate over 160 orders today alone. We will be running our first full production run at 10:00 AM EST this morning. Please let me know what information will best help you diagnose the issue and help us in getting the pend rate down to the 5% - 15% we were anticipating."[185] The same day, but after deployment, Tumblison again emailed the CDM team, informing them that "We just ran our first set of production orders and hit a 59% pend rate. We need to have a call ASAP to discuss a resolution to this issue. Please let me know when we can call."[186] The high pend rate continued in October. [187]

In correspondence to Kroger on October 7, 2013, Johnathon Kuhn of the CDM team explained that he reviewed orders and broke them into the following four categories:

1. Some of the stores were new and the scores were not reliable. This is an SOP issue.

[182] KrogerSmithNMAG00007759.
[183] KrogerSmithNMAG00008085.
[184] KrogerSmithNMAG00008084.
[185] KrogerSmithNMAG00008083.
[186] KrogerSmithNMAG00008082.
[187] KrogerSmithNMAG00007934 (Kroger LPA requesting another meeting with Buzzeo Team to discuss what orders are being pended. "There is concern that the number is higher than expected and continuing to grow each day so we need to discuss as soon as possible").

2. Some of the stores had clearly egregious order sizes. "When a Zscore5range is above 2, it is pretty hard to argue at any level that a pend isn't justified. There are 237 pends where the zscore is above 2 and 177 where it is above 2.5. In nearly all cases, these would have pended earlier in the month."

3. More subtle cases like 35314. "In this case the order mimics the previously largest order. Still it is very significantly above average and 30% above the level of 1 year ago. 62 cases are due to trend4. The model is reacting to what appears to be erratic ordering behavior.

4. There seems to be about 75 close calls. These are the ones that really need human eyes. Most of these would have pended earlier in the month.[188]

In an October 18, 2013, email, B. Williamson of CDM responded to questions concerning pended orders. He advised that stores with a lack of order history have to be handled outside of the SOM model until there is a history.[189] In response to Kroger's assertion that they were unable to process all pended items in a timely manner, Williamson advised that most of the pended orders should be cleared very quickly. In response to the suggestion to change the statistical threshold algorithm, Williamson advised that they only change the model if it isn't working properly.[190] Kroger responded that on October 18 the pend rate was 16%. The LPA team could not process all pended items the previous day so they had to ship some of the items without researching. Further, "[t]his is a big concern for the LPA team and they feel we are pending things that they don't feel should be pended. Dustin and his team have been working to review these orders with Johnathon to see if we have an issue but it looks like the algorithm is working as designed."[191] In response, Williamson advised that "[t]he pend rate of 16% appears high. The usual pend rate is around 3%. The best practice is to investigate all pended orders until cleared." These pend rate problems still existed by the end of October 2013. From October 24 through October 27, pend rates were 23%, 31%, 39% and 44% respectively.[192]

On October 25, 2013, Kroger sent an email to the CDM team saying they pended 674 out of 2,898 pharmacy orders on October 24 and that "this is causing significant concern."[193] In response, on October 28, 2013, CDM explained to Kroger that something is clearly wrong. They believed that the problem was due to the way the history was compiled. They advised that reducing the sensitivity of the model would not work. Kuhn of the CDM team wrote, "To reduce the sensitivity enough to effectively reduce the pend rate would mean that nothing is pended at all. Every indication is that the model is working properly, but either something is wrong with the data that is feeding it or something significant has changed with the business of ordering drugs."[194]

The overall October 2013 Pend Rate was 16.96% and it dropped in November to 10.64%, and in December to 9.01%.[195] In December, the pend rates were in single digits from December 13 until December 20 (when pend rate reached 11.1%). Towards the end of December, pend rates were 21.4%

[188] KrogerSmithNMAG00007761.
[189] See also KrogerSmithNMAG00000889 (the policies and procedures state, "orders with no previous history (e.g., new customer or new ingredient) will pend as an order of interest until there are purchases in 2 distinct months within the last six months on the monitored ingredient in question.").
[190] KrogerSmithNMAG00008061-62.
[191] KrogerSmithNMAG00008061.
[192] KrogerSmithNMAG00007772.
[193] KrogerSmithNMAG00007914.
[194] KrogerSmithNMAG00007913.
[195] KrogerSmithNMAG00007778.

(12/26), 26.5% (12/27), 28.9% (12/28), 24.5% (12/29) and 40.1% (12/30).[196] This trend continued in January where the pend rates were in single digits from January 13 until January 20 (when the rate reached 10.7%). Towards the end of January 2014, Pend Rates were 24.9% (1/26), 32.8% (1/27), 30.5% (1/28), 39.9% (1/29) and 48.5% (1/30).[197] This upward trending of pend rates is consistent with some threshold-based systems. As the amount of product is ordered throughout the month, the amount of ingredient approaches the set threshold or ceiling. Naturally, the pend rates will trigger as orders for specific drugs/items accumulate and are aggregated throughout the month, increasing as the ordering cycle approaches the end of the month.[198] More than 70% of the stores in the Bluffton DC (i.e., Peyton Northern) had pended orders between October 2013 to December 2013.[199]

Upon review of the pending rate for specific drugs in December 2013 and January 2014, the opioids hydrocodone and codeine; the benzodiazepines alprazolam, clonazepam, lorazepam, triazolam and diazepam; and the muscle relaxants carisoprodol, cyclobenzaprine and methocarbamol, all had at least double digit, and in the case of hydrocodone, codeine and alprazolam, triple digit, pend rates.[200] It should be noted that many of these pended orders in January 2014 were appreciably higher that the 0.15 threshold with average pend values for specific ingredients such as: 0.860 for hydrocodone, 0.841 for codeine, 0.859 for alprazolam, 0.868 for clonazepam, 0.873 for lorazepam, 0.951 for triazolam, 0.914 for diazepam, 0.911 for carisoprodol, 0.842 for cyclobenzaprine, and 0.854 for methocarbamol.[201] These drugs are all highly abused as single entities and in combinations such as an opioid and benzodiazepine or an opioid, benzodiazepine and muscle relaxant (cocktail prescribing). Concern that specific pharmacies had high pend rates for two or three of these classes of drugs simultaneously—a suspicious ordering pattern indicative that the pharmacy may not have been performing corresponding responsibility, thus requiring further due diligence—should have eclipsed any concern regarding the global pend rates. However, that was not the case for Kroger. In fact, one of the employees assigned to assist in the development of the SOM program, Jeff Loesch, touted his accomplishment at keeping the identified orders low through algorithm manipulation, and wrote that "The project set out with the goal of creating a process to narrow the orders requiring review to a level between 5 and 15%. A final set of adjustments to the algorithm went into production on 8/20/2014. As of the end of the year, the algorithm was identifying an average of 14% of orders requiring further review."[202] This demonstrates that Kroger was focused on how to control the amount of orders identified for review rather than identifying suspicious orders and preventing diversion. Regardless of the number of orders identified, Kroger should have been focusing on due diligence, e.g., determining why these orders were being placed, and correcting the problems that are triggering the order anomalies.

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[196] KrogerSmithNMAG00007779.
[197] KrogerSmithNMAG00007780.
[198] It was not until July 2016, when Robert Williamson of CDM proposed a change to the statistical threshold algorithm where cumulative strength would be summarizing order strengths in a rolling 30-day period rather than a calendar month period. As discussed, in the calendar month scheme, there is less pending volume at the beginning of each month and high pending volume at the end of each month. Changing to a rolling 30-day calendar would eliminate less pending volume at the beginning of each month and high pending value at the end of each month. This change and the system retunement would reduce the pend rate from 9,000 per month to 3,000 to 4,000 per month. Kroger was impressed with the ability of the CDM solution to reduce the pend rates so significantly and authorized them to move forward with the retunement and further discuss the implementation of the rolling 30-day option in a phased in approach. (KrogerSmithNMAG00007746-7748.). Tumblison recalled that this change was implemented into the Kroger SOM. (Tumblison Depo., at 237:5-8 (Feb. 18, 2022)).
[199] KrogerSmithNMAG00007789.
[200] KrogerSmithNMAG00007782; see also KrogerSmithNMAG00007783 (showing the same substances as ingredient repeat pends in December 2013 and January 2014).
[201] KrogerSmithNMAG00007784-85.
[202] Kroger-MDL00034861.

On February 24, 2014, Kroger representatives met with CDM representatives to discuss the pend analysis.[203] Kroger presented, as "Continued Issues," a continued high pend rate percent at the end of the month, continued high pend values, and the pseudoephedrine ingredient pend percentage.[204] During the meeting, Kroger presented a PowerPoint slide and under the title "SOM Discussion," it explained that there were four additional months of historical data in place, items that contain ingredients that have smaller quantities ordered or dispensed are more suspectable to swings (due to low RX sample size), and suggested considering recalibrating the algorithm with new data in place.[205] Kroger then asked for recommendations moving forward.[206]

On April 8, 2014, Kroger again met with CDM to discuss the SOM. The meeting was described by Meg Sales-Bradley as a meeting to discuss "some details around Koger Company processes and details before we get too far in the retuning of the algorithm."[207] The PowerPoint presentation[208] from this meeting revealed continued high pend rates at the end of the month. Between February 28 and March 26, 2014, 2,467 orders pended compared to March 27 to March 30, 2014, when 2,518 orders pended.[209] Therefore, the increased end of month pend rate continued through March 2014. This trend (large number of pended orders) continued through at least May 30, 2014.[210]

On May 22, 2014, Robert Williamson of CDM sent an email with the subject "Version 2.1," and attached "Kroger Retune v 2.1 May 2014.PDF." This was a corrected version from a previously submitted version[211] and was a "retunement" of the original SOM model that was delivered to Kroger in July 2013.[212] The document explained that the retunement "affords an opportunity to verify and adjust, if necessary, the model coefficients after recalculating them with a more current data set. The periodic adjustment also affords an opportunity for the attributes to be reconfirmed to ensure that the most appropriate order information is collected and analyzed in an appropriate manner."[213] Modifications to the model were made on the DateEffect variable and coefficient values.[214] The May 30, 2014, Suspicious Order Monitoring (SOM) Project #07077 Status Update advised that the Buzzeo Algorithm Enhancements was on target.[215] The Buzzeo enhancements were completed on June 30, 2014.[216]

On June 27, 2014, CDM was notified that order pend rates had declined. Tumblison wrote: "From what the data shows below we were seeing in general a little over 100 pended orders a day (excluding weekends) from the same date range over the last 6 months. The last three days we have seen that number drop to 3 pended orders on Wednesday, and 1 pended order yesterday. While we appreciate the decline in pended orders the extreme decrease has the business (and our team) rather concerned. Was this the expectation from what you had seen in your testing that we would see such a decline in the

[203] KrogerSmithNMAG00007774-98.
[204] KrogerSmithNMAG00007793.
[205] KrogerSmithNMAG00007794.
[206] KrogerSmithNMAG00007795.
[207] KrogerSmithNMAG00007976.
[208] KrogerSmithNMAG00007977-7990.
[209] KrogerSmithNMAG00007986.
[210] See KrogerSmithNMAG00006858-59; KrogerSmithNMAG00006473-74; KrogerSmithNMAG00006852-53; KrogerSmithNMAG00006850-51; KrogerSmithNMAG00006856-57 (all of these documents stated "Large number of items are pending which is creating a backlog and delays in processing orders. Team is working to implement enhancements to improve processing time.")
[211] KrogerSmithNMAG00007731.
[212] KrogerSmithNMAG00007733.
[213] KrogerSmithNMAG00007733.
[214] KrogerSmithNMAG00007733.
[215] KrogerSmithNMAG00006856-57.
[216] KrogerSmithNMAG00006854-55.

number of pended orders?"[217] Johnathon Kuhn of the CDM team responded that he was concerned and "with the last set of validation data" they "began working out what adjustments might be made if the rate didn't" increase. Kuhn suggested changing coefficients for b0 and b11.[218] Kuhn sent this change to Tumblison on July 3, 2014.[219]

By the end of July 2014, the CDM-designed algorithm was still not pending end of month orders. In July 28, 2014 email correspondence, Kroger employee Dan Holtkamp notified Kuhn that during the past weekend the system did not pend a single order and the algorithm "is resulting in nearly no pends after the middle of the month, and even after applying new coefficients there is little impact…"[220] He concluded that he thought there is something wrong with the algorithm.[221] On that same date, Tumblison wrote, "Please let me know if there is anything further we can provide to expedite getting a viable algorithm. After 10 months of having the SOM project go live, we are still having significant resource planning issues in relation to our loss prevention teams. They are currently scheduling staff to come in and review pended orders and then finding that there are none available in the entire shift when there were hundreds the month prior. There are also compliancy concerns at this point since we seem to be making such drastic changes between one month to the next in relation to pend rates."[222]

On August 6, 2014, Tumblison suggested to Kuhn that they revert back to the previous algorithm. Tumblison advised: "Some of the concerns are that we are pending at such a low rate right now it is throwing off all the analysis and forecasting which has been done by the Loss Prevention team and that even though the previous algorithm was pending higher than expected it is still much closer to what we will be seeing in the future with the newest version you are currently working on."[223] Kuhn responded that he would be comfortable waiting until they had more data to make any strong statements.[224]

Kuhn's response was challenged by Meg Sales-Bradley, the Kroger Project Manager, who advised on August 6, 2014, that it was Kroger's belief that the current algorithm was wrong and that pending more is better than missing something that should have pended that they let pass. She requested a reason why they should not roll back to the older version of the algorithm.[225] After several email exchanges on August 6 and 7, 2014, Sales-Bradley agreed that waiting until the end of the month (August) using the new coefficients as the best option.[226] The Algorithm Enhancement implementation occurred on August 19, 2014.[227]

The SOM Status Reports filed on July 18, August 1, August 8, August 15, and August 22, 2014, contained the following statement as Issue 1: "The low number of items pending after implementation of the Buzzeo Algorithm update is causing some concerns and additional review/updates from the vendor. Retuned Algorithm has been received and team is working to test the enhancement. Once it is tested for a full 30 day cycle then team will move enhancement to production environment."[228] This statement was

[217] KrogerSmithNMAG00008267.
[218] KrogerSmithNMAG00008266-67.
[219] KrogerSmithNMAG00008266.
[220] KrogerSmithNMAG00007991.
[221] KrogerSmithNMAG00007991.
[222] KrogerSmithNMAG00007991.
[223] KrogerSmithNMAG00007994.
[224] KrogerSmithNMAG00007994.
[225] KrogerSmithNMAG00008073.
[226] KrogerSmithNMAG00008072.
[227] KrogerSmithNMAG00006873-74.
[228] KrogerSmithNMAG00006854-55; KrogerSmithNMAG00006860-61; KrogerSmithNMAG00006848-49; KrogerSmithNMAG00006862-63; KrogerSmithNMAG00006873-74.

removed from the August 29, 2014, report and was not in any subsequent status report provided to me.[229] However, in the December 12, 2014 status report of the SOM project, the following statement was written under the heading "Project Description": "This is a regulatory/compliance project that will allow us to continue filling lower cost products through Peyton rather than being required to use Cardinal. Pharmacy buyer analysis of losing the ability to handle controlled substances out of Peyton (i.e. Cost of Goods) would be $3.56 MM annually, for a total of $24.89MM over 7 years." This same document reflects a total budget of $400,000 for the SOM project.[230] Kroger clearly recognized by this point that the primary advantage to implementing the new SOM was to save money rather than to identify and prevent the shipment of suspicious orders, or otherwise maintain effective control against diversion.

In 2016, there was discussion to modify the algorithm to a rolling 30-day period rather than a calendar month.

Analysis of the Statistical Threshold-Based SOM Program

My review showed the Buzzeo System could only be as good as the data that powered it, and Kroger's actions with respect to the orders of interest determined how effective the process could be. Seemingly bad data and a focus on workload rather than due diligence indicate Kroger's efforts during Period 2 fell short of identifying suspicious orders and maintaining effective control against diversion.

When the system was initially tested and subsequently deployed in September 2013, Kroger learned that if a pharmacy had historically inflated order volume, subsequent orders may not have been correctly identified by the statistical threshold. They also learned that their SOPs are critical to making sure the stores' orders were appropriate. Nonetheless, the SOPs failed to provide guidance regarding appropriate evaluation and objective assessment of the relevant data necessary to conduct adequate due diligence. The detailed policy and procedure manual included a specific delegation of duties for different employee positions and mandated training. However, the training manual lacked detail regarding how the data fields, historical information, dispensing information, and other related intelligence should be analyzed and evaluated to objectively determine if a suspicious order could be resolved and released or cancelled and reported as suspicious. Making matters worse, historical documents such as pharmacy surveys were disposed of after two years, depriving reviewers of baseline intelligence, location and demographics that are of assistance when conducting due diligence. If genuine due diligence were conducted on orders of interest, reviewers would have had to obtain that lost information (e.g., initial ordering patterns, location, demographics, etc.) for review.

In addition, the statistical algorithm appeared to be inconsistent. Even though CDM assured Kroger that the algorithm was working as intended and even audited the pends and explained to Kroger why many were justified by high scores or a lack of historical data, Kroger complained of the high pend rates and insisted the algorithm needed modifications to decrease the amount of pends. In my opinion, the pend rates indicated ordering anomalies that should have caused concern and triggered enhanced due diligence. Instead of conducing due diligence to dispel suspicion, Kroger continued to request output adjustments. On some dates, Kroger simply shipped pended orders without conducting any investigation because personnel could not investigate them in one day. That was a direct contravention of their obligations under the CSA.

[229] KrogerSmithNMAG00006871-72.
[230] Kroger-MDL00019890-93; KrogerSmithNMAG00006854-55 (July 18, 2014 SOM status update reflecting the total budget as of July 3, 2014 was $400,000).

Kroger only produced four orders identified as "orders of interest" flagged in Cobb County.[231] Two of the orders were in March 2014, one order was in August 2014, and another order was in September2014. It appears that all of the orders were released despite insufficient information to support meaningful due diligence.

Each of these documents identified an order of interest, monthly and cumulative previous orders/shipments, an explanation of what was reviewed to evaluate the orders, and the outcome.

Two of the documents related to Kroger Store number 00365 (Chastain Corners, Marietta GA). The first, dated 03/28/2014 involved hydrocodone. The reviewer noted that there were no previous pends; they reviewed an email, ran one store GCN for the last 90 days; explained that the graph is cyclical and shows no suspicious activity; and that the order was released.[232]

The second incident, dated 03/30/2014, involved tramadol, triazolam and hydrocodone. The reviewer noted that the only product that pended was hydrocodone on 03/28; he/she ran one store GCN for the last 90 days; explained that the "graph looks good on all of them"; noted that the triazolam has been "scratched for the last couple of orders;" identified nothing suspicious and released the order.[233]

The third incident, dated 08/24/2014, related to Kroger Store number 00478 (Shallowford Falls, Marietta GA) and involved hydrocodone. The reviewer identified that the order was reviewed utilizing data from SKOPE and business objects and that there was no suspicious activity found.[234]

The fourth incident, dated 09/29/2014, related to Kroger Store number 00478 (Butler Creek, Ackworth, GA) and involved Pregabalin and hydrocodone. The reviewer noted that the order was reviewed utilizing data from SKOPE and business objects; there was no suspicious activity found; and the order was released. The notes also stated that the "Store sells what they receive in."[235]

These documents illustrate the fundamental weakness in how Kroger evaluated orders.

For example, one of the orders identified involved an opioid (hydrocodone) and a benzodiazepine (triazolam). Anomalies with respect to controlled substance combinations, particularly high dose opioids in combination with benzodiazepines or muscle relaxants, is an indication of diversion. This can also be said for pregabolin and hydrocodone. Therefore, these orders should have caused alarm and triggered a heightened due diligence investigation to specifically include a detailed review of dispensing activities at the pharmacies. Instead, the information reviewed consisted mainly of previous ordering, sales trends, and inventory-related data. Most, if not all, of this information was impractical because it provided data for the drugs by *ingredient volume*, as opposed to drug strength and drug dosage unit, and therefore precluded any meaningful review of the orders of interest in light of the historical ordering patterns. Due diligence efforts were also inadequate for these orders because Kroger failed to conduct on-site visits, there is no documentation of pharmacy contact, if any, and Kroger failed to review or analyze pharmacy dispensing activities.

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[231] Kroger Defendants' Objections and Responses to Track 8 Plaintiff's Requests for Production to New Chain Pharmacy (Dec. 23, 2021); (Request for Production 5). See KrogerMDL00000149, KrogerMDL00000150-55, KrogerMDL00000143-48, KrogerMDL00000137-42.
[232] Kroger-MDL-00000137-142.
[233] Kroger-MDL-00000143-148.
[234] Kroger-MDL-00000149.
[235] Kroger-MDL-00000150-155.

Although Kroger was historically non-compliant with the regulations and guidance letters, and they were attempting to become compliant during 2013, it appears that they failed to take the warnings of DEA and their private consultants seriously. For example, Keith Wilson sent an email discussing a suggestion by the Loss Prevention team that they *shut off the SOM* on Christmas day in 2013, thereby allowing all orders to process as normal, regardless of the SOM implications.[236] He sought input from leadership and their counsel's office, and while he acknowledged that the request was understandable, it would mean that they were making an intentional decision not to be in compliance with DEA "policy." The rationale was that they were already non-compliant since only one distribution center was on the program and they were only reviewing selected items (due to the sheer volume of pended orders). Counsel's office replied that this was not the correct approach to take.[237] First, Wilson's reference to the regulation as a "policy" illustrates that Kroger still misunderstood the binding nature of their suspicious order monitoring obligations. Next, the audacity of this request, as well as the fact that the request actually made its way up through the Kroger corporate ladder to their counsel's office, reinforces my opinion that Kroger still, as late as December 2013, failed to appreciate the importance of the SOM and the consequences of not complying with their legal obligations.

Summary: Analysis and Conclusion

My review period for this engagement was 2006-2014. Based on the documents and depositions that I reviewed, it is my opinion that Kroger did not have a formal SOM during Period 1 and the substitute systems, described as "monitoring orders by collecting and analyzing data pertaining to purchases using computer generated reports," were not compliant SOM systems. None of the SOM methods described could identify suspicious orders for review; they could not stop the orders from being shipped before due diligence could reconcile the suspicious nature of the order; and I was provided with no evidence that suspicious orders were reported to DEA, let alone reported when discovered.

Kroger was aware that the systems utilized during Period 1 were flawed. In a July 2013 document written to describe the scope of the proposed statistical threshold-based monitoring system, Meg Sales-Bradley wrote:

> "The suspicious ordering monitoring program will allow our distribution centers the ability to investigate orders prior to the orders being picked or shipped. Previously, we have used our Loss Prevention Teams to monitor product movement and investigate suspicious activity, *but this was after the product was already shipped to the store and potentially dispensed to customers*. The implementation of an order monitoring program can prevent shipments of suspicious controlled substance orders to stores and inform the distribution center that DEA notification is required if the investigation deems it necessary."[238]

The "Project Risks" section stated emphatically "Kroger is out of compliance – Kroger is out of compliance for SOM until we have a valid process and audit data available."[239]

A DEA guidance letter was sent to all manufacturers and distributors in December 2007 reiterating the requirements of an effective suspicious order monitoring program. This letter included the following cautionary statement: "When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. *Daily, weekly, or monthly reports submitted by a registrant indicating 'excessive purchases' do not comply with the*

[236] Kroger-MDL00155895-56.
[237] Kroger-MDL00155895.
[238] KrogerSmithNMAG00006765 (emphasis added).
[239] KrogerSmithNMAG00006767.

requirement to report suspicious orders, even if the registrant calls such reports 'suspicious order reports.'"[240] Yet Kroger continued to use post-shipment "excessive purchase reports" and failed to implement the statistical threshold-based SOM program for more than five years. The Buzzeo System implemented in September 2013 was too little, too late.

From September 2013 to August 2014, the statistical threshold-based system was operational but either pended too many orders to be researched or pended too few orders (or none at all) for various reasons. Instead of being concerned about the information the orders of interest conveyed (that their pharmacies were displaying indicia of suspicious activity), Kroger was concerned with the workload the high pends put on their staff, and their focus was on reducing the burdens associated with high pends—apparently driven by the desire to clear orders in a single day.

For the vast majority of the reporting period, Kroger did not have a system that was capable of maintaining effective controls against diversion. When Kroger finally did institute a system that had a chance at identifying suspicious orders, Kroger failed to interpret the results as requiring due diligence to dispel suspicion. I therefore conclude that, more likely than not, these deficiencies allowed the flow of controlled substances to Kroger and affiliated pharmacies with some of these drugs ultimately being diverted.

[240] KrogerSmithNMAG00003203 at 3204.

Publix: Diversion Control Policies and Procedures

Introduction

Publix is a grocery/retail store chain headquartered in Lakeland, Florida that operates a regional retail pharmacy chain in several southeastern states. The Publix corporate website states that Publix is the largest employee-owned company in the United States; it is one of the 10 largest-volume supermarket chains in the country; retail sales in 2022 reached $54.5 billion; and it employs over 250,000 people. Publix has 1,346 stores in seven states (Alabama: 88 stores; Florida: 856 stores; Georgia: 206 stores; North Carolina: 53 stores; South Carolina: 69 stores; Tennessee: 55 stores; and Virginia: 19 stores).[241] Publix is the third largest privately held corporation in the United States according to Forbes Magazine.[242]

Publix opened its first pharmacy in 1986 and opened its first store in Cobb County Georgia in 1992.[243] At all relevant times Publix pharmacies dispensed and continue to dispense controlled substances, including those listed on Schedule II. Since 1996, Publix has operated twenty-six pharmacies in Cobb County.[244] During the 2006 to 2014[245] ARCOS review period, Publix operated 24 retail pharmacies located within Publix supermarkets in Cobb County, Georgia. There were 204 pharmacies operating in Cobb County during this time period.[246] Publix distribution facilities only distributed controlled substances to Publix pharmacies and did not distribute controlled substances to any pharmacy outside of the Publix corporate structure.

From at least 2005 to present, Publix distributed Schedule III through V controlled substances to its pharmacies located in its supermarkets in seven states including the State of Georgia and more specifically, Cobb County. From 2006 to 2016, Publix distributed controlled substances from its Sand Lake Distribution Center located in Orlando Florida. In 2016, the Sand Lake Distribution Center closed[247] and all controlled substance pharmaceuticals (and all pharmaceuticals in general) were distributed from the Publix Rocket Court Warehouse ("RCW") in Orlando, Florida.

From 2006 to at least 2014, McKesson (and to a lesser extent Anda, Inc. and River City Pharma/Masters Pharmaceutical Inc.) shipped the vast majority of Schedule II controlled substances, including oxycodone and hydrocodone combination products ("HCPs") after October 2014, to Publix pharmacies in Cobb County.[248] When the RCW opened in 2016, Publix became their retail pharmacies' primary distributor for all Schedule II through V controlled substances.[249]

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[241] www.corporate.publix.com/about-publix/company-overview/facts-figures (accessed 8/4/2023); see also Ottolino Depo. at 17:21 – 18:4 (Dec. 6, 2022) (when Ottolino left in January 2018, Publix was only in six states (adding North Carolina during his tenure to Florida, Georgia, Alabama, South Carolina, and Tennessee) and had over 1200 stores).
[242] www.forbes.com/lists/largest-private-companies (accessed 8/4/2023).
[243] PUBLIX-MDLT8-00132323 (Leonard Dep. Ex. 3); PUBLIX-MDLT8-00115539 (King Dep. Ex. 43; Do Dep. Ex. 16; Ottolino Dep. Ex. 21).
[244] United States District Court, Northern District of Ohio, Eastern Division, In Re National Prescription Opioid Litigation - Cobb County v. Purdue Pharmacy, L.P., et al., MDL No. 2804, Case No. 17-md-2804, Publix Supermarkets, Inc. Supplemental Objections and Responses to Plaintiff's Interrogatories to Chain Pharmacy Defendants (June 16, 2022) at 5-6.
[245] As discussed in more detail herein, I also reviewed ARCOS data related to Publix distributions in Cobb County, Georgia for the period 2015 to 2019.
[246] SLCG, Annual Reports of Opioid Distribution by Distributor/Cobb County/Pharmacy from 2006-2014.
[247] Hewell Depo., at 150:19 – 151:2 (Nov. 4, 2022).
[248] SLCG, Annual Reports of Opioid Distribution by Distributor/Cobb County/Pharmacy from 2006-2014.
[249] Hewell Depo., at 151:9 – 153: 12 (Nov. 4, 2022); SLCG, Appendix 10 Publix, "Opioids Distributed by Publix, by Drug in Dosage Units, Cobb County."

Publix was both a distributor and a dispenser (retail pharmacy) of controlled substances throughout the period of my review. A key in-house advantage to self-distributing is that there are few, if any, obstacles to detecting suspicious orders and obtaining detailed information to support a due diligence investigation and dispel (or confirm) any suspicions associated with an order. However, throughout most of the 2005 to 2020 period, the SOM programs, policies, and procedures utilized by Publix failed to properly detect suspicious orders, investigate, and dispel suspicion associated with those orders, or maintain effective controls against the diversion of controlled substances.

Publix was aware that suspicious order monitoring was a requirement under the CSA and implementing regulations. In addition to the DEA guidance letters sent to all distributors in 2006 and 2007,[250] Publix was again reminded of their obligations in 2008 when McKesson, their Schedule II supplier, was fined $13.2M and was required to start a controlled substances monitoring program. This information was passed to Publix employees during a DVP (Divisional Vice President) meeting in May 2008 regarding pharmacy procurement.[251] Despite their knowledge, Publix failed to establish effective SOMs throughout the period of my review.

In my review, I found that the programs, policies, and procedures utilized by Publix were inadequate to identify and stop suspicious orders and were therefore ineffective at maintaining effective controls against diversion. The absence of formal operational Suspicious Order Monitoring ("SOM") policies, lack of adequate training and guidance, and limited resources and support prevented suspicious orders from being appropriately identified and reviewed and allowed potentially suspicious orders to be shipped to Publix pharmacies. Furthermore, I found that Publix created an environment ripe for filling controlled substance prescriptions not issued for a legitimate medical purpose through their failure to provide adequate training and policies and procedures to their pharmacy supervisors, pharmacists, and technicians related to due diligence, thresholds, and the subsequent review and analysis of controlled substance prescriptions, including performing corresponding responsibility and identifying red flags.

Publix did not have consistent, uniform methods or procedures designed to identify and report suspicious orders until 2012 (at least 7 years after they initiated Schedule III – V controlled substance distribution from the Sand Lake Distribution Center in Orlando, Florida) and they did not report any suspicious order to DEA until 2018.[252] In fact, it was not until 2016 that Publix began using an automated program, E-Supply Link, that was specifically designed to help detect suspicious orders. As discussed in detail below, Publix lacked appropriate resources to manage and operate this system, and it was an ineffective method to detect suspicious orders because it failed to detect all of the suspicious order criteria.

Publix has claimed that from 2005 to the 4th quarter of 2012, its Publix Inventory Management System ("PIMS") was utilized to monitor for suspicious orders. The PIMS Ship Maximum Quantity ("SMQ") allowed Publix pharmacies to order, without review or oversight, up to a pre-set maximum amount of any product on a single order, while omitting any amounts in excess of the maximum quantity.[253] As discussed later in this report, PIMS was quantity/volume based, functioned as nothing more than an inventory control system, could be easily circumvented, and failed to identify orders that were of unusual size or frequency, or that deviated substantially from a normal pattern.

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[250] See PUBLIX-MDLT8-00147285.
[251] PUBLIX-MDLT8-00073500-502; see also Publix MDLT8-00073491 – 492; Ottolino Depo., at 242:10-244:20 (Dec. 6, 2022) (testifying that because Publix only distributed to their own pharmacies, they are not considered a "wholesaler," implying that they are not subject to regulations applicable to controlled substance distributors).
[252] Hewell Depo., at 178:7-185:13 (Nov. 4, 2022).
[253] Publix-MDLT8-00067296.

Also, during this same timeframe (2005-2017), Publix did not submit any suspicious order reports to DEA.[254] The first suspicious order was reported in 2018.[255] Approximately 94 "orders of interest" related to Cobb County were identified by the Publix SOM system in 2016. None of these 94 orders were reported to DEA as suspicious, and I have not been provided with any materials to suggest that Publix conducted due diligence adequate to dispel the suspicious nature of the orders. Between 2016 and May 2021, approximately 1,200 orders of interest were identified by the Publix SOM related to Cobb County.[256] However, from 2005 to 2020, Publix did not report to DEA a single suspicious order related to a Cobb County Publix pharmacy.[257]

Another troubling deficiency in the Publix SOM concerned their due diligence on flagged orders. Orders flagged by the Publix SOMs were not reviewed by anyone until 2012 (supervisors reviewed from 2012 to 2018; diversion analysts began review in 2018/2019[258]). Instead, Publix purportedly relied on their "systems," i.e., PIMS, to review the flagged orders.[259] However, PIMS did not review anything other than the quantity of controlled substances ordered. While the systems could identify orders based on a given set of criteria, only a person with the proper knowledge, training, and experience can conduct adequate due diligence based on the specific and individual surrounding facts and circumstances necessary to determine whether an order is suspicious and then report it to DEA.

In summary, (from December 2005 to July 2020, the Publix programs, policies, and procedures did not qualify as a SOM system in compliance with 21 CFR 1301.74(b). The systems only identified orders that reached a certain quantity/volume or threshold, and failed to monitor patterns or frequencies, two additional criteria specified in 21 CFR 1301.74(b). More importantly, these systems did not provide the necessary processes to maintain effective controls to prevent the diversion of controlled substances. Only beginning in July/August 2020 did Publix have the technical capabilities, resources, procedures, policies, training, and centralized leadership necessary to operate a compliant SOM program. Nonetheless, I have not been provided with ARCOS data or materials demonstrating how Publix executes the SOM implemented beginning in 2020.

SOM systems should identify pharmacy orders/purchases that are suspicious and cause the distributor to focus due diligence efforts to determine or resolve suspicious nature of the order. A common reason for suspicious orders is failed corresponding responsibility analysis at the pharmacy, a deficiency at the pharmacy on evaluating, analyzing, and resolving certain indicators or red flags when filling a controlled substance prescription. If the pharmacist is not vigilant when performing this required process, and instead continues to fill prescriptions with red flags, more drug seekers will come to the pharmacy seeking to have illegitimate prescriptions filled. One of the best ways to stop diversion at the pharmacy level is to have policies and procedures in place that guide a pharmacist in approaching corresponding responsibility analysis and how to recognize fraudulent or altered prescriptions. However, Publix did not add this guidance to its Regulations and Associated Publix Policies (R and P Manual) until July 25, 2012.[260] Previous editions released on July 19, 2010[261] and April 27, 2012[262] did not have this guidance. Publix recently published a pharmacy reference and procedure guide dated May 11, 2022, that

[254] Hewell Depo., at 31:23 – 32:10 (Jul. 25, 2023).
[255] Hewell Depo., at 31:23 – 32:14 (Jul. 25, 2023).
[256] Hewell Depo., at 40:18 – 43:22 (Jul. 25, 2023).
[257] Hewell Depo., at 31:23 – 34:3 (Jul. 25, 2023).
[258] There is some conflict on the exact year the diversion analysts started, with Hewell stating 2018 and J. Smith testifying that they were hired in 2019.
[259] Hewell Depo., at 139:13 – 23 (Nov. 4, 2022).
[260] PUBLIX-MDLT8-00027405 – 7449.
[261] PUBLIX-MDLT8-00003532 – 3571.
[262] PUBLIX-MDLT8-00023196 – 3236.

expanded guidance within chapter 8, Regulations and Associated Publix Policies.[263] If corresponding responsibility is not performed appropriately and the SOM is not performing appropriately, similar to Publix in Cobb County, the system is ripe for diversion.

Below, I evaluate in detail the Publix programs, policies, and procedures related to SOM during Period 1 (2005-2012), Period 2 (4th quarter 2012 to 3rd quarter 2016), and Period 3 (3rd quarter 2016 to June 2020). I also discuss the programs, policies, and procedures during Period 4 (June 2020 to present), but I am unable to fully evaluate them due to a lack of information regarding their actual implementation.

Period 1: 2005 – 2012

Publix Inventory Management System ("PIMS")

Publix described PIMS as their first suspicious order monitoring system to identify and flag orders.[264] PIMS was a technology tool that operated between 2005 and 2012.[265] Simply put, PIMS was an inventory control system that prevented pharmacies from ordering too little or too much of a particular product. Chris Hewell testified that PIMS established a conservative maximum shipment amount ("PIMS Ship Max") that a pharmacy could order based upon warehouse ordering patterns.[266] I have not been provided with any documents that list the Ship Max Quantity ("SMQ") assigned to Cobb County Publix pharmacies or any other Publix pharmacy within the chain.

In an April 5, 2014, document titled, *Pharmacy Procurement Department Processes,* PIMS SMQ was defined as follows:

> Ship Max quantities are the maximum amount of an item (in full containers) that can be purchased on a single order from the Publix Pharmacy Warehouse. Ship maximums are entered when the item is created and periodically reviewed by the Pharmacy Manager of Procurement.
>
> When a Publix Pharmacy Warehouse order is transmitted to the warehouse for a quantity that exceeds the Ship Max, the order is only fulfilled to the maximum quantity and the remaining quantity is omitted.

In explaining the inventory management process, Fred Ottolino testified that there is a minimum and a maximum number for "…every product, controlled, non-controlled, how we manage inventory." Ottolino advised that they put numbers in the system for every drug to ensure that there is enough inventory available for sale. For example, Ottolino explained that if for a particular drug they wanted to make sure there were at least 100 tablets on the shelf in case a customer needed it, but not more than 300 tablets on the shelf, the minimum would be 100 tablets and the maximum would be 300 tablets.[267] The PIMS system would reduce orders to a standard size and any amounts above the established maximum would be omitted. The PIMS did not require a due diligence review prior to reducing the flagged orders. For the reasons discussed herein, PIMS was not a compliant SOM during this period.

The PIMS SMQ process could be easily circumvented. The SMQ is based on a particular item or NDC, therefore controlled substances of the same drug/strength could be ordered from different

[263] PUBLIX-MDLT8-00126452-916.
[264] Hewell Depo., at 45:6 – 9 (Jul. 25, 2023).
[265] Hewell Depo., at 45:6 – 25 (Jul. 25, 2023) (Publix began using PIMS in 2005 as a technology tool that was part of the suspicious order monitoring system during that time); Hewell Depo., at 179:23 – 180:9 (Nov. 4, 2022).
[266] Hewell Depo., at 57:8 – 24 (Jul. 25, 2023).
[267] Ottolino Depo., 214:11 – 216:24 (Dec. 6, 2022).

manufacturers or in different package quantities without triggering a flag or causing the order to be reduced to the SMQ. Therefore, a Publix pharmacy could avoid detection and successfully order an unusually large quantity of a controlled substance in the same dosage strength (e.g., hydrocodone 10 mg) by ordering multiple manufacturers' products and/or ordering in multiple package/bottle sizes. The same pharmacy could then order multiple bottles per day of hydrocodone 7.5 mg and hydrocodone 5 mg because they are different item numbers, and still not trigger the SMQ. Another feature that compounded these weaknesses was that Publix allowed pharmacies to order the same controlled substance multiple times per week without regard for the total amount ordered.

Yet another way Publix pharmacies could easily circumvent the Publix PIMS SMQ process was to avoid PIMS altogether and order from a third-party vendor, because PIMS only reviewed Publix Warehouse orders and did not capture third-party vendor orders.[268]

Even when Publix pharmacies' orders went through PIMS, the orders identified above the PIMS SMQ should have been treated as potentially suspicious orders requiring due diligence. Yet no materials were provided to me that indicate any due diligence was conducted on these orders. Testimony revealed that there was no individual employee assigned to review orders that were reduced to the SMQ.[269] Instead, Publix relied on "the system" to review the orders.[270] High-volume ordering above a threshold or outside a normal ordering pattern should have triggered a due diligence review of the physician prescribing and pharmacy dispensing patterns within these stores. Due diligence should include a review of dispensing data to identify the physicians that are prescribing the drugs, their medical specialties or disciplines, drug combinations/cocktails and a review of corresponding responsibility/dispensing practices at the requesting pharmacies. Simply reducing or eliminating unusually large controlled substance orders (i.e., orders above the SMQ) does nothing to dispel the suspicion raised by the fact that these pharmacies were dispensing controlled substances above the expected/anticipated quantities, nor does it relieve Publix of the responsibility to investigate the pharmacy to determine why their orders are over maximum and to notify DEA when a suspicious order is discovered. Shipping the orders without dispelling their suspicious nature violates the requirement that Publix stop suspicious orders, as well as their obligation to maintain effective controls against diversion.

Thresholds: Setting the PIMS SMQ

There were several deficiencies with respect to the manner in which Publix set the PIMS SMQ. Minimum and maximum values were set at the organization level, as opposed to the individual store level; the SMQ was applied to each item, as opposed to each drug or drug family; and the SMQ ignored ordering frequency and patterns.

In testimony, Hewell explained that the "PIMS ship max" is a "conservative maximum" amount that a pharmacy could order that was set at the organization level and not at the individual store level. The PIMS system had the capability to consider individual store utilization to set the ship max.[271] However, prior to 2012, PIMS did not allow a threshold to be set for each specific pharmacy. Instead, the max ordering point/SMQ was based on all store utilization (all stores taken together) and not a specific store (individualized by pharmacy). This lack of individualization was a fundamental inadequacy of the system as a tool for suspicious order monitoring. This system operated from the first day Publix started

[268] Hewell Depo., at 53:14 – 19 (Jul. 25, 2023).
[269] Hewell Depo., at 139:21 – 140:5 (Nov. 4, 2022).
[270] Hewell Depo., at 139:11 – 23 (Nov. 4, 2022).
[271] Hewell Depo., at 56:23 – 58:16 (Jul. 25, 2023) (also noting that future iterations (4th Quarter 2012) of PIMS allowed Publix to set a threshold by pharmacy).

distributing (December 2005) until 2012.[272] This explanation confirms my opinion that Publix had no SOM during Period 1 and the PIMS was merely an inventory management tool.

I have not been provided with any materials that explain how Publix calculated the SMQ for particular drug items, nor have I been provided with specific SMQ minimum/maximum values in place during Period 1. However, if for example the SMQ is 5 bottles of 100 for a particular item, and there are multiple manufacturers/bottle sizes each with a different NDC/item code, a pharmacy could easily order a significant amount of a particular drug/strength without affecting the SMQ, rendering the SMQ insignificant except as an inventory tool.

The PIMS SMQ is threshold-based for size/volume only and disregards frequency or substantial deviation from a normal ordering pattern. By definition, an order that exceeds the SMQ would be an order of "unusual size." A system that only identifies unusual size is not in compliance with the provisions of 21 CFR §1301.74. However, because the SMQ was set at the institutional level, the system would not detect orders that were suspicious due to a volume anomaly, yet of smaller total volume (e.g., a pharmacy orders significantly more than normal based on its own history, yet the total volume is below the institutional maximum).

The automated inventory system was basically making the determination on the amount to ship so the order would not be stopped. The PIMS SMQ system was never designed to be a SOM. This is obvious, considering the many ways in which it could be easily circumvented, and that it only tracks order size based on inventory expectations, disregarding frequency or orders that substantially deviate from a normal pattern.

Due Diligence and Identifying Suspicious Orders

When asked who was reviewing controlled substance orders on a daily basis, Hewell responded that certain orders were reviewed and explained that Publix had centralized review of Schedule II orders since the 2000s. He identified this ordering system as CSOS (the Controlled Substance Ordering System).[273] CSOS is a secure, DEA-operated, automated ordering system for Schedule II – V controlled substances. However, CSOS is not a SOM application. This was confirmed in an August 2012 email that Hewell sent to a Meijer employee in August 2012 requesting information and "any documentation on what your CSOS signers use to screen for suspicious ordering." The Meijer employee responded that the CSOS reviewers ("signers") did not have anything on the approval side to screen orders and CSOS approval is only meant as a mechanism to verify the actual source and destination of the orders and not the content.[274]

In April 2014 (during Period 2), Publix issued a process titled Controlled Substance Ordering System (CSOS) Excessive Order Review, directing Administrators to evaluate orders for reasonableness prior to signing them. The document explained that order points are set by the Central Inventory Management Tool that increases or decreases the Min/Max values according to the pharmacy's actual usage of drugs. When a pharmacy orders more than their normal usage, the CSOS Administrator needs to verify the usage prior to signing the order to determine if the large quantity is appropriate for the pharmacy or if the quantity is too high. This is determined using dispensing history, current inventory, allocated inventory from recent prescription activity and prescription hard copy review. If the quantity ordered is too high, it must be sent to the Manager of Procurement for authorization or cancellation.[275] As

[272] Hewell Depo., at 58:21 – 60:10 (Jul. 25, 2023)
[273] Hewell Depo., at 136:5 – 137:5 (Nov. 4, 2022).
[274] Publix-MDLT8-00065877.
[275] Publix-MDLT8-00067299.

Publix was not distributing Schedule II substances at this time, Publix instituted this policy to monitor Schedule II controlled substances purchased from McKesson. Publix clearly understood their obligations with respect to order reviews, and this could have been an effective tool to review suspicious ordering patterns on the Schedule II side when Publix was reviewing/investigating Schedule III – V orders at the Publix warehouse during Period 2.

During Period 1, any orders that exceeded the SMQ were automatically cut back to the SMQ without any due diligence to dispel the suspicious nature of the orders. As previously stated, this type of oversight/review of orders does not help the distributor understand why a pharmacy is attempting to order large quantities, or to determine if the pharmacy is conducting corresponding responsibility on incoming controlled substance prescriptions. Cutting the order to the SMQ does not resolve the suspicious nature of the order, nor does it relieve Publix of the duty not to ship the order unless the suspicion is resolved. It also does not prevent the pharmacy from obtaining the excess quantity that was cut by simply placing a new order whether it be with the Publix distribution center itself or an outside vendor like McKesson or Anda.

Large quantities of controlled substances, especially high dose, combination opioid products, benzodiazepines and muscle relaxants should have been reviewed and questioned by Pharmacy Supervisors or the Pharmacy Operations section in Publix headquarters since they should have an understanding of why these products were being ordered in large quantities to better determine if there is a problem at the pharmacy level. If they ship up to a limit and hold the remaining drug or simply cancel the remaining order, Publix never determines why the pharmacy was ordering the quantities that it did. Meanwhile, if there are suspect prescriptions from suspect doctors being filled at the pharmacy, they continue to get filled in competition with legitimate prescriptions that are also presented for dispensing. In this cycle, due diligence is not accomplished, and the true nature of the suspicious order is never determined. Therefore, shipping the orders up to a certain quantity and holding or cancelling the remaining quantities without establishing if the order is truly suspicious violates the registrant's requirement that they maintain effective controls against diversion.

No due diligence was performed during Period 1 based on my review of depositions and documents provided to me. It is concerning that Publix did not have due diligence files on pharmacy orders/activities as late as 2011 and relied solely on the SMQ to meet SOM requirements. An August 2011 email exchange between Hewell and Jason Bamberger (Orlando DC Superintendent) discussed a DEA request regarding a Publix due diligence/new customer application. Bamberger explained to the DEA that Publix should have a process in place soon but because they are in "a closed circuit", they "hadn't needed something like that." Bamberger further explained that Publix had max ordering points, so they "had somewhat of a net."[276] Bamberger recognized that Publix "would need to have some form of report that would be viewed by pharmacy ops and flag suspicious orders."[277] This statement shows that the system, at least up until August 2011, was not compliant with the PIMS as the foundation. It is evident, based on the Bamberger statement, that nobody was reviewing orders, flagging suspicious orders, or reporting orders of interest/suspicious orders inside or outside of Publix.

Training

I was not provided with any materials that indicate that anyone involved in the PIMS/SMQ process was trained or otherwise educated on controlled substance diversion. There was no formal written training or guidance to assist employees performing the review process (due diligence) or that they were provided with objective criteria that assisted employees in resolving a suspicious order flagged

[276] PUBLIX-MDLT8-00065740.
[277] PUBLIX-MDLT8-00065740.

by the PIMS. There is no specificity in the *Pharmacy Procurement Department Processes* to determine what criteria, procedures, or metrics are used to determine if the purchases in excess of the maximum order quantity are indeed suspicious, and what would determine whether the excess over the SMQ should freeze the whole order for investigation and if not resolvable, reported.

Without designating employees who are specifically tasked with and dedicated to reviewing orders and providing them with basic information concerning methodology as simple as identification of normal or abnormal ordering frequency patterns, or determining what constitutes a substantial deviation from a normal pattern, suspicious order identification will be difficult at best. Without guidance on how to objectively review breaches of SMQ or item purchase limits there could be no consistent review of orders.

There are no SOPs issued/published in Period 1 that I reviewed that describe the policies and procedures that guide the employees through the process of evaluating orders under review and allow for partial orders to be shipped before an evaluation of the order or due diligence is conducted. There was no guidance or training on how an order is to be evaluated to reconcile the suspicious nature of the order.

Reporting Suspicious Orders

Publix did not report any suspicious orders during Period 1. Hewell testified that the PIMS system flagged orders dating back to 2005, but he could not provide details of the number of orders flagged because they were destroyed/purged prior to depositions.[278] He testified that orders identified by PIMS from 2006 to 2016 were purged pursuant to the Publix document retention policy prior to the deposition and were not available.[279] I reviewed the document retention policy in the R&P Guide dated July 25, 2012[280] and found no specific guideline for retention of due diligence files, orders of interest, or suspicious orders. Publix's failure to require the preservation of its records of flagged orders is yet another instance of the inadequacy of its system for suspicious order monitoring. As discussed, this type of information is crucial when establishing a foundation for a SOM so that historical purchase patterns and questioned orders can be reviewed during the due diligence process. These files should be retained for all customers indefinitely and should be accessible to all employees who perform due diligence.

Other System Components

Hewell testified that there were other review processes related to the Publix SOM during Period 1. For example, if a pharmacy was ordering more product than they were dispensing, a Loss Prevention intervention would be initiated.[281] This type of review is generally designed to detect and deter employee pilferage, a very specific type of diversion, which, unlike most other forms of diversion, results in financial loss to Publix. A Loss Prevention intervention does nothing to identify potential problems related to corresponding responsibility or the entry of a new prescriber in the area that may not be prescribing for a legitimate medical purpose, or to prevent other forms of diversion that do not result in financial loss to Publix. Even so, an internal Publix document from August 2018 (Period 3) makes clear that Publix's loss prevention and loss reporting capabilities and processes were woefully inadequate.[282] As late as August of 2019, Publix still needed to "assess and clearly define requirements of DEA and state regulations" and was looking to "identify potential sources of significant loss discovery. . . and develop a

[278] Hewell Depo., at 47:1 – 15 (Jul. 25, 2023)
[279] Hewell Depo., at 49:10 – 50:21 (Jul. 25, 2023)
[280] PUBLIX-MDLT8-00027432-434
[281] Hewell Depo., at 140:7 – 141:3 (Nov. 4, 2022)
[282] PUBLIX-MDLT8-00088571-577.

process to notify Pharmacy Compliance and Regulatory Affairs" once losses were detected.[283] Publix was still planning for full centralization of loss reporting as well as coordination with Loss Prevention ("LP") in November of 2019.[284]

Hewell also testified that Publix "advised our pharmacies to also review manual inventory adjustment reports … with the intent that our pharmacy supervisors are trying to identify what a real suspicious order is; in other words, an order that could potentially be diverted…."[285] He went on to say that they are looking at some of these metrics to determine whether or not there is pilferage with manual inventory adjustments. They are also looking at the dispensing activity and comparing it to other pharmacies.[286] When asked if everything he listed in that review occurred from the first day of distribution (2005) through 2016, Hewell responded, "no."[287] In fact, the only materials provided to me that mention this type of review were published in Period 2 in 2014.[288]

The system that Publix utilized during Period 1 should have been far more expansive than identifying employee pilferage and should have been designed to identify all controlled substance orders that are suspicious, i.e., orders that are of unusual size, frequency and deviating substantially from a normal pattern, as required by 21 CFR 1301.74(b). Again, I was not provided with any policies or procedures related to the PIMS being utilized for the SOM during this time period, nor was I provided with any training materials that describe processes, policies or procedures to investigate flagged orders, or training to help employees conduct reviews of flagged orders. Even so, all orders that exceeded the PIMS SMQ should have been investigated. Diversion has many forms, the most prevalent and destructive being inappropriate dispensing of prescriptions not issued for a legitimate medical purpose. Merely scaling back orders fails to maintain effective controls against diversion.

Analysis of the PIMS System

It is my opinion that there was no SOM in place during Period 1 as required by 21 CFR 1301.74(b). The PIMS system described by Publix was an inventory management system that Publix did not use to identify or report suspicious orders during Period 1. Publix put forth PIMS as their SOM post hoc. This is clear from the fact that the system does not identify orders of unusual frequency or orders that deviate substantially from a normal pattern, the absence of review for omitted orders, the absence of training to help determine if an omitted order is suspicious; the fact that no suspicious orders were reported to DEA during this time period, and the multiple, easy methods to circumvent the PIMS or obtain larger quantities than the system limits.

[283] Id. at 575.
[284] PUBLIX-MDLT8-00079714-716.
[285] Hewell Depo., at 64:23 – 65:5 (Jul. 25, 2023)
[286] Hewell Depo., at 65:6 – 65:12 (Jul. 25, 2023)
[287] Hewell Depo., at 65:21 – 66:2 (Jul. 25, 2023)
[288] PUBLIX-MDLT8-00067275-307

Period 2: 2012/4th Quarter[289] – 2016/3rd Quarter[290]

Enhanced PIMS Order Omits and Orders of Interest

The system that operated during Period 2 was an enhanced version of PIMS that operated between 2012 and 2016.[291] The enhanced PIM system utilized a threshold.[292] By October 15, 2012, the thresholds would reset at the beginning of each month,[293] however, in 2018 the threshold was based on a 30-day rolling period (rather than a calendar month).[294]

Period 2 saw Publix's first documented SOM-related policy dated December 13, 2012. The process was titled *Pharmacy Warehouse Controlled Substance Auditing Policy Program*.[295] This policy described the following "new" auditing features that were being implemented:

- Establishment of a monthly threshold by drug molecule (basic class) for each pharmacy. Thresholds are determined by an analysis of an individual pharmacy historical purchasing patterns and dispensing trends
- Publix will monitor accumulated monthly units shipped from the warehouse for all controlled substances and thresholds will reset at the beginning of each month
- Pharmacies that are close to reaching controlled substance threshold (typically 85%) will be notified by an automated Order Quantity Warning for Controlled Substances EMAIL that is sent to pharmacy and Pharmacy Supervisor.[296]
- If a pharmacy reaches a controlled substance threshold, it will be notified by an Order Quantity Violation for Controlled Substances EMAIL. No additional units will be shipped to the pharmacy for the remainder of the month without submitting a Controlled Substance Threshold Request Form
- If a pharmacy requires a higher monthly allocation, the Pharmacy Manager must fill out a Controlled Substance Threshold Request Form and send to the Pharmacy Supervisor and Pharmacy Operations Manager for approval.
- Once a threshold change is approved by the pharmacy supervisor or Pharmacy Operations Manager, the Pharmacy Procurement Department will update the item management system with the change, and additional product can immediately be ordered that month[297]

The Period 2 system had three new features of note during this time period.

First, each pharmacy was still assigned an SMQ, but the SMQ was determined by taking into account store usage.[298] During Period 2, the PIMS prevented pharmacies from ordering above the SMQ for any

[289] Hewell Depo., at 60:14 – 17 (Jul. 25, 2023).
[290] Hewell Depo., at 78:1 – 13 (Jul. 25, 2023).
[291] Hewell Depo., at 180:10–18 (Nov. 4, 2022).
[292] Hewell Depo., at 182:9 – 182:18 (Nov. 4, 2022).
[293] PUBLIX-MDLT8-00118720.
[294] PUBLIX-MDLT8-00130895.
[295] PUBLIX-MDLT8-00098667.
[296] See also Hewell Depo., at 66:19 – 22 (Jul. 25, 2023) (Hewell admitted that during Period 2, it was at times Publix policy to notify a store if it was approaching its controlled substance threshold); PUBLIX-MDL-T8-00067297 (email notification is sent to the pharmacy and Pharmacy Supervisor when the pharmacy is approaching their threshold and when they have exceeded the threshold.).
[297] PUBLIX-MDLT8-00098667; see also PUBLIX-MDLT8-00118720 (dated 10/15/2012).
[298] Hewell Depo., at 58:3 - 16 (Jul. 25, 2023).

pharmaceutical including controlled substances, and if the threshold (described below) was breached, it caused all controlled substances of the same basic class in the order to be omitted.

Second (and new to Period 2), Publix established a monthly threshold by drug molecule (basic class) for each pharmacy. Thresholds were determined by an analysis of an individual pharmacy's historical purchasing patterns and dispensing trends. A significant weakness with the Publix basic class (drug molecule) threshold-based system is that it was based on the total volume of tablets without regard for the strength of the individual dosage form of the controlled substance. For example, a pharmacy may be situated in close proximity to a surgical center that may need to prescribe large quantities of a low dose opioid for acute pain relief of recently discharged patients. The pharmacy's quantity ordered might be at threshold or just under threshold and on its face, the volume may look unusual, but the low dose nature of the product and the specialty of the surrounding medical facilities may support the monthly volume, so the threshold is set appropriately. However, the dynamics change when the vast majority of the controlled substances ordered is a high dose opioid that is not related to a particular specialty. So, if the majority of the controlled substances ordered by a particular pharmacy is a high dose opioid, but it does not breach the threshold, this ordering pattern is suspicious regardless of the threshold and should be reviewed. A threshold-based system that does not consider the strength of the drugs within the basic class ordered is overlooking an important component of suspicious order monitoring and fails to identify orders deviating substantially from a normal pattern. In the Publix threshold-based system, if the threshold is never breached, the ordering pattern would not be flagged. Even so, as discussed below, order reviewers had little to no training on what to look for in their due diligence investigations, and reviewers were not instructed to review particular drug strengths to determine the high dose to low dose ratio and the justification for this type of ordering pattern.

Third, if the threshold was breached, the Pharmacy Supervisor was notified of the flagged item, and he/she was supposed to review it to determine whether it was suspicious. In other words, once the order gets flagged by PIMS because of a threshold breach, the product was not shipped (it was omitted) and pharmacies and pharmacy supervisors were notified of the flagged order. The Pharmacy Supervisor was supposed to determine whether or not the pharmacy needed a threshold increase and whether there was activity that would warrant the flagged order being deemed suspicious.[299]

The Publix SOM process institutionalized dispelling suspicious orders by increasing the threshold, a cycle that was ripe for abuse. If a threshold is breached the order is omitted and sent to the Pharmacy Supervisor for review. Meanwhile, a threshold increase request is submitted to the same Pharmacy Supervisor who is tasked with conducting due diligence on the same order. If the Pharmacy Supervisor increases the threshold, the suspicious nature of the original order causing the breach is ostensibly dispelled.

Threshold Changes

Based on the materials provided to me, it appears that threshold changes were a mainstay in Publix's ability to avoid suspicious order reporting while increasing sales. Throughout Period 2, Publix notified their pharmacies when they were approaching their threshold, thereby providing an opportunity to increase the threshold before it could be breached.[300] In addition, as noted above, Publix pharmacies received a warning email before the item quantity was made zero. Upon notification, the Pharmacy Manager could submit a threshold change request to the Pharmacy Supervisor to increase the basic class

[299] Hewell Depo., at 61:14- 62:4 (Jul. 25, 2023).
[300] PUBLIX-MDLT8-00115176; note this notification was discontinued during SOM Period 3 and no notification was given before an item was zeroed out due to a flagged order.

threshold for that particular pharmacy.[301] If approved, the pharmacy could immediately order additional quantities of the item that was omitted up to the new threshold.

It was unreasonable for Publix to provide threshold limit warnings to their stores. Providing this information in advance gives the pharmacy the opportunity to structure orders to avoid threshold breaches (and omits) and the additional scrutiny (albeit minimal) from a due diligence review. Furthermore, it provides the Publix pharmacy with the opportunity to find an alternate source to purchase controlled substances and circumvent the Publix system. The process as executed gives the impression that it is common for threshold increase requests to be approved. There were very little materials made available to me concerning threshold increases for particular pharmacies during the period when thresholds were the foundation of the system.

Threshold change requests created an increased workload for the Pharmacy Supervisors who ultimately approved the threshold increases with little or no due diligence (discussed below). The benefits to Publix by increasing thresholds were obvious. The increased thresholds avoided the omit, in turn avoiding a disruption in shipments and allowing controlled substances to continue to flow to their pharmacies upon request, at least until there was a new threshold close call, and the cycle started over again. The threshold increase was the solution to suspicious order reporting when it should have been a trigger point to investigate and report. An omit (i.e., a cancelled or reduced order) does not excuse Publix, or any other distributor, from the obligation to determine why the breach occurred and to conduct due diligence to determine whether the order was truly suspicious.

Another weakness in the Period 2 system was that the Pharmacy Supervisors had a personal financial interest in maximizing the sale of pharmaceuticals. Publix's Pharmacy Supervisors are paid a bonus based on Publix sales and profit.[302] Therefore, the Pharmacy Supervisors have an incentive to ensure that drugs continue to flow out of the pharmacy to maximize profit. History has provided numerous examples of chain drug stores and their pharmacists disregarding their obligation to perform a corresponding responsibility analysis on incoming prescriptions in the interest of meeting prescription volume goals for personal or store incentives, or because they were too busy to take the time to conduct this analysis, and instead continued to fill prescriptions.[303] Since this incentive is also felt upstream at the Pharmacy Supervisor level, it is likely that this incentive influenced Pharmacy Supervisors to approve threshold increases without conducting adequate due diligence and without appropriate justification.

For example, on August 4, 2015, a threshold change request was submitted to ANDA through the Pharmacy Ops chain for a 10% increase in oxycodone with the justification that the pharmacy continued to grow RX volume at a rate of 30% versus last year, and the pharmacy "ran out" of Percocet at the end of July and was running low on several other drugs containing oxycodone. The change request was submitted at 10:30 am and approved by the Pharmacy Supervisor 40 minutes later at 11:25 am. The

[301] Hewell Depo., at 66:13 - 18 (Jul. 25, 2023).
[302] Hewell Depo., at 160:9 – 16 (Nov. 4, 2022). Additionally, a quarterly bonus was rewarded to Pharmacy Managers, Assistant Managers and 30-hour pharmacists that included the stores profitability and the total prescription count of the pharmacy. Publix-MDLT8-00059249 (Do Depo. Exh. 7 (Nov. 16, 2022)).
[303] "United States Reaches $22 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances," (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution#; "Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act," (Jan. 12, 2009), https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations; "Walgreens Agrees to Pay A Record Settlement of $80 Million for Civil Penalties under the Controlled Substances Act," (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled#.

justification provided should have triggered a review to determine why there was an increase in oxycodone dispensing at this particular pharmacy and a review of what strengths were being dispensed, which doctors are prescribing, and whether the patients receiving the oxycodone are new patients or long-term patients that receive other medications from the pharmacy. The pharmacist should also have been questioned about the increase in oxycodone dispensing. The justification statement raises more questions than leaves answers, and the Pharmacy Supervisor's only documentation of his review is "approved." ANDA adjusted the pharmacy's limit.[304]

On March 28, 2016, a threshold change request was submitted to ANDA through the Pharmacy Ops chain for a 30% increase in oxycodone with the justification "As of 3/25/16, we did not have enough oxycodone 10/325 to fill our Rxs. As of 3/26/16, we do not have enough oxycodone 7.5/325 to fill our Rxs. We will run out of oxycodone 5/325mg in the next few days." The change request was submitted at 10:46 am and approved by the Pharmacy Supervisor two minutes later at 10:48 am. The justification provided should have triggered a review to determine why there was such an increase in oxycodone dispensing at this particular pharmacy and a review of what strengths were being dispensed, which doctors were prescribing, and whether the patients receiving the oxycodone are new patients or long-term patients that receive other medications from the pharmacy. It is very concerning that the low dose oxycodone combination product remained in stock, but the higher dose products were out of stock. Again, the pharmacist should have been questioned about the increase in oxycodone dispensing. It is difficult to understand how any investigation, let alone an adequate investigation, could have been accomplished in a 2-minute time frame, especially with a 30% increase requested. Again, the justification statement raises more questions than leaves answers, and the Pharmacy Supervisor's only documentation of his review is "approved."[305]

In another example, on March 31, 2016, a threshold change request was submitted to ANDA through the Pharmacy Ops chain for a 30% increase in oxycodone 15 mg and 30 mg with the justification, "We have a number of regular customers who take these as maintenance meds, on whom we check the PDMP to ensure compliance." The change request was submitted at 3:25 pm and approved by the Pharmacy Supervisor four minutes later at 3:29 pm. The justification should have triggered a review because the two drugs mentioned in the justification, oxycodone 15 mg and 30 mg are highly sought after for abuse purposes. The pharmacist should have been questioned about the reason these drugs are being used as maintenance meds and if the increase in prescribing of these high dose single entity opioids are driving the increase. Additionally, the Pharmacy Supervisor should have determined the ratio of high dose to low dose oxycodone prescribing, the doctors that are prescribing these drugs and their specialties, and whether the patients receiving the oxycodone are new patients or long-term patients that receive other medications from the pharmacy. Again, the pharmacist should have been questioned about the increase in oxycodone dispensing. It is difficult to understand how this could have been accomplished in a four-minute time frame, especially with a 30% increase requested. The justification statement raises more questions than leaves answers and the Pharmacy Supervisor's only documentation of his review is "30% approved."[306]

In another example, on May 2, 2016, a threshold change request was submitted to ANDA through the Pharmacy Ops chain for a 20% increase in oxycodone with the justification, "We have met our threshold and need to increase to meet our customer's needs." The change request was submitted at 6:40 pm and approved by the Pharmacy Supervisor two minutes later at 6:42 pm. The lack of justification should have triggered a review because it does not address what is driving the increase that caused a threshold breach. The pharmacist should have been questioned about the increase in prescribing and

[304] Anda_Opioids_MDL_0000335480-482.
[305] Anda_Opioids_MDL_0000344122-123.
[306] Anda_Opioids_MDL_0000343756-757.

whether it is driven by high dose single entity and combination opioids; the ratio of high dose to low dose oxycodone prescribing; the doctors that are prescribing these drugs and their specialties; and whether the patients receiving the oxycodone are new patients or long-term patients that receive other medications from the pharmacy. Again, the pharmacist should have been questioned about the increase in oxycodone dispensing. It is difficult to understand how this could have been accomplished in a two-minute time frame, especially with a 20% increase requested. The justification statement raised more questions than provides answers and the Pharmacy Supervisor's only documentation of his review is "approved."[307]

All of the preceding examples involved Georgia pharmacies outside of Cobb County. There are other similar examples reviewed in which the due diligence was inadequate to support an increase.[308] The systemic incentives to approve threshold changes without appropriate investigation or justification was compounded by other factors. In my experience, the Pharmacy Supervisors were unable to adequately perform the necessary due diligence to determine if an order was suspicious and also justify a threshold increase. There was just not enough time, not to mention training, as evidenced by the testimony of some pharmacy supervisors.

I reviewed a small number of threshold change requests from Publix pharmacies operating in Cobb County, Georgia. On July 1, 2015, Pharmacy 0033 in Marietta, Georgia submitted a request for a 100 tablet increase in Alprazolam 0.5 mg to Pharmacy Operations Manager R. Michael King and Pharmacy Supervisor Jennifer Layton. The reason for change indicated they "now have nearly none on hand." There was no document that reflected an adjudication of this request.[309]

On July 9, 2015, Pharmacy 0566 in Acworth, Georgia submitted a request for a 500 tablet increase in Oxycodone 10/325. The reason for change indicated, "We ran out by June 20th last month and had to send regular customers away. Already, my system is trying to order more (based on computer generated order points) and I am not getting any from Anda due to threshold limits." There was no document provided that reflected an adjudication of this request.[310]

For each of these requests, little information was provided to justify a threshold change, which should have triggered additional questions. For instance, they may inquire as to what is driving the increased use of the particular controlled substance, have there been threshold increases within the last 3 months and has there been an increase of out-of-area patients. This is not all inclusive list and the questions should be tailored to the particular drug and the dispensing practices of the particular pharmacy.

Finally, on March 1, 2017, Pharmacy 0561 in Marietta, Georgia submitted a request for a 180 tablet increase in Hydromorphone 4 mg to Pharmacy Supervisor Leigh Anne Jacobson and Pharmacy Operations Manager R. Michael King. The reason for change indicated, "We have a patient who just transferred >14 prescriptions to our pharmacy from CVS Target and he will be getting 180 hydromorphone 4 mg every month. Our request to order was denied and the medication was not sent".[311] There was no document provided that reflected an adjudication of this request. In this case, it would be helpful to understand the medical condition for which this patient is being treated. This dosage regimen of hydromorphone exceeds 90 MMEs which increases the potential risk of overdose. It would be important to review all of the patient's medications and potential drug interactions, diagnosis, and other documented therapeutic concerns before the threshold increase is approved and the drug dispensed.

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[307] Anda_Opioids_MDL_0000343326-327.
[308] See Anda_Opioids_MDL_0000296241 – 244 and Anda_Opioids_MDL_0000343115 – 116.
[309] Publix-MDLT8-00140766.
[310] Publix-MDLT8-00140855.
[311] Publix-MDLT8-00069637.

Pharmacy Supervisors were required to supervise a large number of stores on a daily basis. Michael Chavez estimated that during the 13 years he was a Pharmacy Supervisor he supervised between 35 to 42 stores.[312] That is a large number of stores for which to provide oversight, especially when the Supervisor must conduct due diligence to determine if an order is suspicious and also entertain threshold increases (in addition to other job responsibilities).

Chavez explained that if he received notification of a suspicious order and he did not have the information from the store from past communications, he would talk to the store about the reasons for the need and to make sure that if the threshold is increased, it is justifiable.[313] He could not recall if he ever categorized an order as suspicious during his tenure as Pharmacy Supervisor between 2008 and 2018.[314] He said if he did have a suspicious order, he would deny a request for an increased threshold.[315] Even if there was a suspicious order, he would not know where to look to query the order and did not know where those records were kept.[316] Finally, he was asked how he documented the process of determining if a threshold increase was justified and he responded that he did not know if there was a specific document for that process. When asked again if there was a specific document explaining why the increase was granted and what indices were reviewed to make the decision, Chavez stated, "So there may be, but it would be somebody else. It's not going to be mine."[317]

Another Pharmacy Supervisor, Leigh Anne Jacobson, provided similar testimony. She has been a Pharmacy Supervisor since 2016 and at the time of her deposition she had 34 pharmacies under her supervision. When she started in 2016, she had approximately 41.[318] One of her jobs was to investigate the initial threshold request looking at utilization of the drug and evaluating the prescription to make sure it would be appropriate to accommodate.[319] She would look at "the whole usage."[320] She stated that her first question is whether another pharmacy closed or something else like a new prescriber or increased growth. She would also review a drug utilization report.[321] Documentation for her due diligence was done on email, "So that would be the best record of what I would have recorded but may not, as exampled [sic], include every detail of my research."[322] She also said she received the threshold change requests with some frequency.[323] She was asked to define suspicious order and she responded that "I have an understanding of it and what that means for the pharmacy, but I don't want to mis—misspeak about what its official definition is."[324] She agreed that it is not her role or responsibility to determine if certain orders are suspicious or not. She has never reported a suspicious order or decided that an order is suspicious.[325] It should be noted that Jacobson started her inquiry on threshold increase by looking at whether there was a store closing or new prescriber in the area or increased growth. However, as I have said previously, a store could be closing because of violations discovered through investigations by Federal or State agencies and a new practitioner in the area could be illegally prescribing, causing

[312] Chavez Depo., at 87:12 – 17 (Dec 14, 2022); see also Chavez Depo., at 119:8 – 11 (Dec. 14, 2022) (between 2017 and 2018 he supervised approximately 40 or 41 stores).
[313] Chavez Depo., at 206:16 – 207:4 (Dec. 14, 2022).
[314] Chavez Depo., at 207:15 – 209:17 (Dec. 14, 2022).
[315] Chavez Depo., at 209:18 – 210:1 (Dec. 14, 2022).
[316] Chavez Depo., at 210:21 – 211:3 (Dec. 14, 2022).
[317] Chavez Depo., at 221:5 – 223:9 (Dec. 14, 2022).
[318] Jacobson Depo., at 18:11 – 19:5 (Nov. 8, 2022).
[319] Jacobson Depo., at 319:3 -319:16 (Nov. 8, 2022).
[320] Jacobson Depo., at 320:1 - 320:18 (Nov. 8, 2022).
[321] Id.
[322] Jacobson Depo., at 322:20 - 322:22 (Nov. 8, 2022).
[323] Jacobson Depo., at 329:7 -18 (Nov. 8, 2022).
[324] Jacobson Depo., at 246:1 – 247:9 (Nov. 8, 2022).
[325] Jacobson Depo., at 247:10 – 248:6 (Nov. 8, 2022).

increased prescription traffic and growth. There is no mention of this real possibility in any of the material provided to me.

Publix pharmacist and Cobb County pharmacy manager Shannon Brice testified that in her experience at Publix, when an order that she placed was flagged or held up for some reason she would usually receive an email notification that the order had been approved within 24-48 hours.[326] Pharmacist Brice also testified that in her experience most of the orders that were flagged were at some point approved.[327]

Due Diligence and Flagged Order Reviews

Hewell testified that from 2012 to 2016 Pharmacy Supervisors were reviewing "orders of interest" or flagged orders generated from the enhanced PIMS,[328] and from 2012 to 2018 the pharmacy supervisor was determining if an order was suspicious.[329] The criteria they used was whether or not the pharmacy was filling illegitimate prescriptions or was diverting product.[330] When asked what they did to check if the pharmacy was filling illegitimate prescriptions, however, Hewell replied that he was "not certain what their entire process was."[331]

In addition to the examples discussed above, there were other indicators that pharmacy supervisors were not appropriately conducting due diligence. For example, in a compliance team memo dated November 10, 2015, Ashley Greathouse discussed four Publix stores that had two increases over McKesson's purchase allocations during the 3rd quarter, 2015, and stated that the pharmacies' sales were up "dramatically," and pharmacies requested small increases which were "far smaller than their demand required," requiring them to request a second increase. They determined that no corrective action needed to be taken.[332] McKesson was the primary supplier of Schedule II controlled substances to Publix during this time period. Contrary to the meeting notes, an increase in demand has no bearing on the legitimacy of orders—particularly a "dramatic" increase in demand. Instead, the due diligence review should expose what is causing the increased demand and if the increase is due to factors other than legitimate prescriptions.

Fred Ottolino, VP of Pharmacy, did not appreciate why these increases are important and why they should be documented. During testimony, he was questioned about the rationale for multiple increases and where it is documented, and he responded, "Well, I'll tell you the thinking through the process, other than volume increase in a specific location, be it for a new physician or a new store, would be the rationale for an increase. There were—you know, what else are you going to document, other than my business is growing."[333] When asked if it was documented if the request was denied, Ottolino testified that what happened in the past is not an indication of what is happening currently. He went on to say that the necessity to document why an increase was requested is not impactful information, stating "Why would we spend resources in doing that. I guess I'm trying to understand why we would want to do that? There's no value in that."[334] What Ottolino fails to understand is that a historical perspective of increases above a threshold, and in some cases decreases, is the foundation of a SOM investigation

[326] Brice Depo., at 41:14-42:3.
[327] Brice Depo., at 42:4-8.
[328] Hewell Depo., at 139:4 – 11 (Nov. 4, 2022); see also Hewell Depo., at 138: 11 - 23 (Nov. 4, 2022).
[329] Hewell Depo., 161:8 – 15 (Nov.4, 2022).
[330] Hewell Depo., 161:17 – 21 (Nov.4, 2022).
[331] Hewell Depo., 161:22 – 162:2 (Nov.4, 2022).
[332] PUBLIX-MDLT8-00147776-777.
[333] Ottolino Depo., at 207:20 – 210:18 (Dec. 6, 2022)
[334] Ottolino Depo., at 210:25 – 214:10 (Dec. 6, 2022)

(starting threshold, threshold increases, and current threshold) and hold great value in the due diligence analysis. While store growth can happen for any number of reasons, due diligence is only adequate if it uncovers whether the reason for growth is legitimate. In the business growth scenario, the question to be answered is whether business is growing because the pharmacy is filling illegitimate prescriptions, or for some other legitimate reason. For example, a new prescriber may be in the area and his/her prescriptions are driving the increase in order volume. Adequate due diligence would look at his/her specialty and the drug/dosages he/she is prescribing; in addition, the pharmacist would be questioned about his/her prescribing habits and patients. What is normal for an oncologist is not necessarily normal for family practice. This is the essence of due diligence, and it should be documented so that the next person conducting due diligence has a historical record of the patterns and practices at the specific pharmacy under review. Put simply, the fact that a store's opioid business has grown is a reason to begin a diligent inquiry, not a justification for failing to perform one.

It is also important to note that, in 2008 when McKesson notified Publix that it was changing its processes with respect to "monitoring the ordering and distribution of controlled substances," Publix failed to reflect on how *it* was monitoring the ordering and distribution of controlled substances ostensibly because Publix was not a "wholesale" distributor.[335] Dain Rusk, Ottolino's successor and Publix's current VP of Pharmacy similarly misstated Publix's obligations stating that Publix "is not a distributor."[336] This after-the-fact rationale for failing to adequately identify and stop suspicious orders is disingenuous. Publix is registered with DEA as a "distributor," and multiple letters from DEA to Publix in 2006 and 2007 emphasized their responsibilities with respect to suspicious orders without distinction between "wholesale distributors" and distributors as a whole.

Note that Period 2 was the time period when the Pharmacy Supervisors were handling the review of orders that have breached a threshold, before the first algorithm-based system. This same situation also occurred in the 4th quarter of 2015, as evidenced by a compliance memo detailing another conversation about stores requesting two increases during the quarter which was described in the memo as a severe hazard. According to the memo, the team discussed this metric and agreed that it was not a good measure for measuring the illegal dispensing of controlled substances. Adam Maingot advised the team that there was a new SOM in place that flags orders of 5,000 controlled substances or multiple frequent orders of controlled substances and then reports to DEA those orders that are determined to be suspect. The team agreed to change the metric to the number "of suspicious orders of controlled substances reported to DEA through the SOM system."[337]

Training, Policies and Procedures – Due Diligence and Threshold Changes

According to Hewell, Pharmacy Supervisors were provided with criteria to determine if dispensing activity is suspicious to include reviewing the dispensing history of the pharmacy and determine whether or not the prescriptions being dispensed were suspicious. He also testified that they sent out monthly reporting to the Pharmacy Supervisors to provide a trending report of their assigned pharmacies. That included the percentage of controlled prescriptions and cash pay patients.[338] However, no materials were provided to me to establish that this was done in Period 1. Instead, the materials I have reviewed indicate that this information/guidance was first introduced in Period 2 when individual pharmacy thresholds were attached to the PIMS. This is supported by a document copyrighted by Publix

[335] Ottolino Depo., at 241-45 (indicating that Publix only distributed internally, and therefore it was not considered a "wholesale distributor" like McKesson); PUBLIX-MDLT8-00147270.
[336] Rusk Depo.. at 54-56. Rusk further testified that it was his belief that Publix was not a "wholesaler" stating, "I don't know that I understand the laws." *Id.* at 55.
[337] PUBLIX-MDLT8-00147778-779
[338] Hewell Depo., at 64:6 – 20 (Jul. 25, 2023); see also PUBLIX-MDLT8-00147628.

in 2013 and released in April 2014 titled "*Controlled Substance Anti-Diversion Processes.*"[339] This document explains the threshold concept and provides guidance suggesting that Pharmacy Supervisors should visit pharmacies that have exceeded their thresholds to determine the need for a threshold increase and determine if any suspicious activity is taking place. It also directs the Pharmacy Supervisors on how to report suspicious activities.[340]

This 2014 document also discussed the reports generated for each pharmacy's dispensing history for high diversion controlled substances which is used to identify and evaluate trends in dispensing, compare pharmacy controlled substance dispensing with similar volume pharmacies, and recommend adjustments to thresholds. It also contained individual store count of all controlled substance prescriptions dispensed, percent of all controlled substance prescriptions to overall prescriptions, count and percentage of prescriptions for individual controlled substances, count of controlled substances filled cash or discount card, and percentage of controlled substances filled cash or discount card.[341] Interestingly, the Publix form used by Publix pharmacy supervisors when visiting their stores makes no mention of suspicious orders or any review of order history while on store visits.[342]

As discussed, once an order was omitted, the only way a pharmacy could procure additional product was for the Pharmacy Manager to submit a threshold request form and obtain approval from the Pharmacy Supervisor to increase the threshold for that particular pharmacy.[343] Formal training or guidance dated July 2018 (during Period 3) was intended to assist Pharmacy Supervisors in reviewing threshold change requests,[344] and it appears to be the first threshold training guidance for Pharmacy Supervisors with approval authority. Of significance is that the use of thresholds started approximately six years earlier, in 2012, so it appears that prior to 2018 (i.e., during Periods 1 and 2), Publix Pharmacy Supervisors had no formal guidance on how to review orders of interest or what to look for when adjudicating threshold change requests. Furthermore, as described later in this report, the training/guidance provided in July 2018 document is flawed, could create confusion, and fails to provide adequate information to make an appropriate determination. Interestingly, the Publix form used by Publix pharmacy supervisors when visiting their stores makes no mention of suspicious orders or any review of order history while on store visits.

Reporting Suspicious Orders

According to Hewell, between 2012 and 2018, an "order of interest" (triggered by breaching the threshold) was omitted, and the Pharmacy Supervisor that reviewed the order had no ability to get the item appended back to the order. The order was not reported to DEA because it was not determined to be suspicious.[345] The Pharmacy Supervisor would review the order and determine if it was suspicious. If they determined it was suspicious, they would notify procurement (Chris Hewell) via email or telephone, and Hewell would notify the warehouse and DEA.[346] Orders of interest were not treated as suspicious orders but instead were designated orders of interest until there was additional evidence.[347]

[339] PUBLIX-MDLT8-00067275 – 7306.
[340] PUBLIX-MDLT8-00067297.
[341] PUBLIX-MDLT8-00067298.
[342] PUBLIX-MDLT8-00076593-596.
[343] PUBLIX-MDLT8-00098667.
[344] PUBLIX-MDLT8-00130893 – 895.
[345] Hewell Depo., at 165:24 – 166:12 (Nov. 4, 2022).
[346] Hewell Depo., at 166:18 – 168:1 (Nov. 4, 2022).
[347] Hewell Depo., at 164:23 – 165:11 (Nov. 4, 2022).

Between 2012 and 2018, Hewell did not receive any suspicious order notification from any Pharmacy Supervisor, and therefore Hewell did not report any suspicious order to DEA during that period.[348] Hewell could not provide a precise number of Publix pharmacies that were operating during that time period, but he estimated that it was close to 1,000 as they approached 2018. When asked if he was concerned that Publix did not report a single suspicious order between 2012 and 2018, he replied that since the orders of interest were omitted, there was no chance to fulfill the order during that timeframe.[349] Of course, that would be true only if there was no threshold increase. In any event, omitting these suspicious orders without reporting them or conducting due diligence on them fails to maintain effective controls against diversion. A distributor's SOM is an alert system that notifies the distributor there may be a problem with a particular order of controlled substances that requires further investigation. Omitting the order that breaches the threshold, combined with increasing the threshold with little or no due diligence, leads to an unresolved suspicious order. There is never a resolution as to why the pharmacy was ordering the quantities that caused the threshold breach, allowing potential diversion to perpetuate.

The Drug Enforcement Administration conducted a scheduled in-depth on-site investigation of the Publix Sand Lake Distribution Facility (DEA Registration RP0331924 for Schedules 3, 3N, 4 and 5) on July 14 and July 15, 2015. According to the DEA-6 Report of Investigation, Hewell advised that there is a threshold process in place and the pharmacy can increase threshold pursuant to a request process, which determines if an increase in threshold is necessary. Publix maintains a history of any/all threshold adjustments for each customer. Hewell stated to DEA that the firm not only reviews the customer purchase history but also has the ability to review the customer's dispensing activity. In fact, on July 17, 2015, Hewell provided to DEA a spreadsheet of thresholds for selected pharmacies that included the number of units ordered vs. the number of units shipped.[350] Hewell advised that he was aware of the DEA requirements for reporting suspicious orders and confirmed that Publix had not reported any suspicious orders to DEA.[351] However, in his deposition testimony, Hewell stated that all data and documents have retention guidelines and this data was no longer available. He eventually testified that it was destroyed.[352] Therefore, I was not provided with a complete record of the established thresholds and subsequent changes by pharmacy during this time period to understand how threshold was established, or how threshold requests were being reviewed, processed, and justified. However, I was able to review a small snapshot of threshold change requests made available to me, and I found very little information to justify approvals. Furthermore, the justifications for threshold increases provided by the pharmacies should have triggered a full due diligence review including how corresponding responsibility is performed in the pharmacy.

In September 2015, Publix began shopping for a new SOM solution in anticipation of opening a new warehouse that would be distributing Schedule II controlled substances. The application that they were considering cost approximately $350,000. They were reviewing an application from Axway (a CSOS provider), that was a tool that can be included with CSOS. Hewell made clear that Publix needed a more robust SOM process to ship Schedule II controlled substances. He wrote, "Without a better solution than our current, we stand the risk of regulatory fines and loss of DEA licensure." Hewell was asked whether Publix needed the existing Schedule III controls to be included in the scope of the project and he advised that the SOM application should focus on the Schedule IIs and they could roll out the other controls in a separate project.[353] In this email chain, the Assistant Compliance/Regulatory Manager, Laura Slone wrote, "I probably should not side bar with you but…The only requirement for us with SOM

[348] Hewell Depo., at 168:18 – 165:11 (Nov. 4, 2022).
[349] Hewell Depo., at 169:14 – 170:6 (Nov. 4, 2022).
[350] PUBLIX-MDLT8-00067262.
[351] DEA-T711CC-00010761-0775.
[352] Hewell Depo., at 222:15 – 226:4 (Nov. 4, 2022).
[353] PUBLIX-MDLT8-00143498 -514

is to report it. The DEA does not tell us how. It would appear that AXWAY is throwing in a "sun roof" at a $353 cost. The only other thing I see is could this be added on later through them…Yes."[354] Ultimately, E-Supply Link was hired for the project.[355]

Based on her email, it is evident that Ms. Slone, who was the Assistant Compliance/Regulatory Manager, did not fully understand the distributor's responsibilities under 21 CFR 1301.74(b). It is true that DEA does not tell the distributor what system to use to monitor for suspicious orders. Rather, the system utilized must be tailored to the specific business model of the registrant. However, it is not accurate that the only requirement for the distributor under the SOM is to simply report suspicious orders. The requirements go beyond reporting. As discussed above, a compliant SOM system should employ analytics, historical data, pharmacy level dispensing data, and other detailed information from pharmacy personnel to resolve suspicion surrounding a particular order.

During the 1st quarter of 2016, the compliance team was told that there were no suspicious orders reported through the system. Fred Ottolino asked if the system was in place and implemented and Maingot responded there was a current system in place for Schedule III – V substances. The compliance team meeting memo revealed that, as of April 29, 2016, the Publix warehouse was distributing Schedule II drugs, and they had purchased and were piloting new software that would be "fully implemented at some point in the future."[356] It should be noted that Publix did not start warehousing Schedule II controlled substances until October 2016 in the new Rocket Court Warehouse facility in Orlando FL.[357]

In the 2nd Quarter of 2016, there were still no suspicious orders reported to DEA. According to the compliance team meeting memo, as of July 22, 2016, the system was operational for Schedule II drugs. In addition, Ottolino advised the compliance team that there were controls in place to make sure associates did not use other distributors to obtain the same scheduled drugs.[358] This is contradicted by Zillgitt in a memo dated July 31, 2018, in which he stated "Also, even if an order were stopped by the Suspicious ordering system, the store could simply purchase the drugs from the wholesaler."[359]

Analysis of the Enhanced PIMS Program

The system utilized in Period 2 was not much of an upgrade from the PIMS/SMQ system of Period 1. The most significant change was the addition of a threshold measuring volume (the unusual size component of 21 CFR 1301.74(b)). Other changes included: the whole order being omitted once threshold is breached rather than being scaled back to the established SMQ; the requirement that Pharmacy Supervisors review the order and determine if it is suspicious; and the Pharmacy Supervisors being provided with the authority to approve threshold increases that are requested by pharmacies under their supervision. However, the system still had major flaws, did not comply with 21 CFR 1301.74(b), and failed to maintain effective control against diversion.

[354] PUBLIX-MDLT8-00143498.
[355] Hewell Depo., at 207:22 - 24 (Nov. 4, 2022).
[356] PUBLIX-MDLT8-00147781-782.
[357] United States District Court, Northern District of Ohio, Eastern Division, In Re National Prescription Opioid Litigation - Cobb County v. Purdue Pharmacy, L.P., et al., MDL No. 2804, Case No. 17-md-2804, Publix Supermarkets, Inc. Supplemental Objections and Responses to Plaintiff's Interrogatories to Chain Pharmacy Defendants (June 16, 2021) at 4.
[358] PUBLIX-MDLT8-00147783-7784.
[359] PUBLIX-MDLT8_00147800.

First, the system was still threshold-based for volume only, and disregarded orders of unusual frequency and substantial deviation from a normal ordering pattern, the other two criteria for a suspicious order. Since threshold-based systems only monitor one of the three criteria established in 21 CFR 1301.74(b), the Publix system was not compliant. Furthermore, the system was volume based for total quantity of dosage units ordered and failed to consider the individual dosage strengths ordered. For example, if a pharmacy had only ordered one high-dose product within a basic class but remained under the volume threshold, the Publix system would not have identified the ordering pattern anomaly. Even if an order breached the threshold and was being reviewed by a pharmacy supervisor, suspicious order identification would be difficult to impossible absent basic information concerning methodology as simple as identification of normal or abnormal order frequency patterns, or determining what constitutes a substantial deviation from a normal pattern.

Second, formalized policies, procedures, and training related to threshold breaches did not occur until April 2014 (*Pharmacy Controlled Substance Auditing Program*) when Pharmacy Supervisors were directed to visit pharmacies that exceeded thresholds to determine the need for a threshold increase and determine if any suspicious dispensing activity is taking place.[360] This guidance adds very little to establishing a methodology and falls far short of guidance to investigate the breach to determine why it occurred and whether the cause was legitimate. It also did not explain what procedures should be taken to investigate the breach or how to determine if a threshold increase is justified. Furthermore, since the breach is a flag that requires a suspicious order determination, there should be policies and procedural methods that are outlined with factors, instruction, and guidance to explain how to evaluate whether an order is suspicious and whether a threshold should be increased. The employees responsible for investigating suspicious orders were Pharmacy Supervisors, not trained regulatory investigators, and therefore a standard, uniform methodology to approach the evaluation of a suspicious order and threshold request is an essential element of a compliant SOM system. The threshold system description was published in both a Pharmacy Procurement Update in October 2012[361] and Pharmacy Warehouse Controlled Substance Auditing Policy and Program in December 2012,[362] but neither of these documents discuss or direct Pharmacy Supervisors to evaluate threshold breaches to determine whether the order causing the breach is legitimate. Both of these documents discuss what happens when a threshold breach occurs and how to submit a threshold change request to justify additional threshold quantity. It makes no reference to Pharmacy Supervisors determining if the threshold breach and the corresponding order is suspicious. This confirms that in Period 2 Publix institutionalized using threshold increases to avoid identifying suspicious orders.

Third, the Pharmacy Warehouse Controlled Substance Auditing Policy and Program in December 2012 states that "thresholds are determined by an analysis of individual pharmacy historical purchasing patterns and dispensing trends." This too is problematic. Since the threshold system was new, there was no previous system in place to determine if the prior order orders were unusually large/suspicious. Therefore, a store that could have been dispensing medications pursuant to suspect prescriptions would have a much higher threshold than what was legitimately needed. Basically, the historical patterns that established the thresholds could have been improperly inflated at the start of the new threshold-based system. Inflated thresholds will allow suspect pharmacies to avoid breaches.

[360] PUBLIX-MDLT8-00067297.
[361] PUBLIX-MDLT8-00118720.
[362] PUBLIX-MDLT8-00098667.

Finally, no suspicious orders were reported during Period 2 for Cobb County—or the whole Publix chain—despite the fact that in a 44-week time period starting on April 13, 2015, non-Schedule II orders averaged 2,937 per week (total of 129,267 orders in 44 weeks) and Schedule II orders averaged 1,716 per week (total of 75,527 orders in 44 weeks).[363]

Period 3: 2016/3rd Quarter[364] – June 2020

E-Supply Link (Third-Party System)[365]

As noted above, Publix transitioned to a new warehouse beginning August 16, 2016. The new warehouse was scheduled to begin shipping Schedule II controlled substances after all Publix pharmacies were converted to it in September 2016. [366] In conjunction with this transition, from 2016 (3rd Quarter) to June 2020, Publix utilized E-Supply Link, a third-party system.[367] E-Supply Link was an algorithm-based system that made available 17 different test options to evaluate orders.[368] Each of the 17 tests in the algorithm evaluated size, frequency, or pattern.[369] Publix initially utilized multiple tests for their SOM, however, too many orders "errored out" (i.e., were flagged as potentially suspicious) which would have made it difficult for Publix to service their stores.[370] Accordingly, Publix decided to only use test #3, testing for size (order quantity).

Despite having no background in controlled substance compliance, Jillanne Smith was promoted in August 2018 and took over the centralization project that included suspicious order monitoring.[371] She was not aware of what tests (for the algorithm) were turned on when she took over.[372] When questioned about a store ordering from outside vendors, she stated that it would be concerning if a store could purchase something, and Publix would not be able to consider that purchase.[373] She testified that she could not say whether Publix was reporting suspicious orders prior to her taking over the centralization project.[374] Once centralization was complete, Smith's department took over the approval process for threshold increases.[375]

[363] PUBLIX-MDLT8-00067907-909.
[364] Hewell Depo., at 85:6 – 14 (Jul. 25, 2023) (referencing an E-Supply Link Report of Flagged Orders beginning in September 2016).
[365] In March 2016, E-Supply Link provided a SOMLink User Guide to Publix to assist in updating SOPs for the new warehouse opening and inspection. (PUBLIX-MDLT8-00143536; PUBLIX-MDLT8-00143405). The user guide provided a step-by-step explanation of the process and function of the system that was deployed in the 3rd quarter of 2016. (PUBLIX-MDLT8-00124145-174). I was not provided any materials that were prepared during Period 3 that explained the system functions and procedures, such as updated SOPs.
[366] PUBLIX-MDLT8-00118734.
[367] Hewell Depo., at 180:24 – 181:3 (Nov. 4, 2022); see also Hewell Depo., at 125:18 – 126:3 (Jul. 25, 2023); PUBLIX-MDLT8-00071321 (when Publix Warehouse began shipping controlled substances in October 2016, the decision was made to use an outside vendor, E-Supply link, as the Suspicious Order Monitoring Program).
[368] PUBLIX-MDLT8-00071321.
[369] PUBLIX-MDLT8-00071323 – 327.
[370] PUBLIX-MDLT8-00071321.
[371] Smith Depo., at 29:13-31:22, 229:18–25 (Nov. 15, 2022).
[372] Smith Depo., at 215:4-23 (Nov. 15, 2022).
[373] Smith Depo., at 216:12–217:6 (Nov. 15, 2022); *see also* PUBLIX-MDLT8-00147800.
[374] Smith Depo., at 181:9–183 (Nov. 15, 2022).
[375] Smith Depo., at 231:23–232:18 (Nov. 15, 2022).

A November 2018 Operations Update stated that "Centralization of controlled substance compliance is important to Publix." The document listed three initiatives that were in progress to develop centralization of controlled substance compliance to include:

- Suspicious Order Monitoring (centralized the identification and evaluation of orders of interest to the Pharmacy Compliance Department that evaluated the orders for initial approval (or not). Orders not approved are investigated further to determine if it's a reportable incident or not reportable to DEA. The document also states that, "It's important to note that any orders not approved are evaluated for partial orders and such to ensure that we are appropriately handling customers in the process." The document also stated that Publix is replacing a major component of the order monitoring system and has selected a vendor and are in the contracting process;
- Diversion Analytics (monitoring the dispensing patterns associated with controlled substance dispensing patterns by evaluation of basic metrics potentially leading to an investigation of controlled substance dispensing activity); and
- Significant Loss Reporting (reporting of losses of controlled substances).
- The Centralization process also included controlled substance training, centralized the reporting of inspections from any agency to Compliance and Regulatory Affairs for analysis, internal reporting, remediation and responses; and provided for a new continuing education provided for pharmacist and technician CE for licensure.[376]

In April of 2019, Publix was still in the planning phase of its journey towards compliance, as evidenced by the Joint Pharmacy Compliance Proposal prepared by Jillanne Smith and other members of the newly centralized compliance team.[377] The proposal listed, among other things a suspicious order monitoring program, a diversion analytics program and a significant loss program as CS programs that "need[ed] to be fully developed" to complete the goal of centralization, recognizing that this was "an essential step to becoming a compliant, best-practice industry leader."[378] Included in the proposal was a request to hire two hourly (not salaried) diversion analysts who would focus on analyzing "purchasing and dispensing activity, along with other available data to determine if an order is in fact suspicious or not."[379]

Algorithms and Thresholds

On April 20, 2018, Publix employees met to develop recommendations to improve the algorithms behind the tests. The main recommendation was that they update how to calculate the average for test #11 (frequency). In a subsequent meeting on April 23, 2018, Publix asked E-Supply Link to review how they were calculating the average and asked them to look at actual rather than daily (they were dividing by the days in a month and not considering the number of days they receive orders).[380] Publix also decided to utilize Test # 17 to evaluate pattern, which was started on April 23, 2018.[381]

During the April 23, 2018, meeting, Publix was advised by E-Supply Link that the thresholds utilized by the system were set to "As Needed" which meant that if there was enough history, and the growth over the threshold limit was reasonable, the threshold would not be enacted, allowing the store to receive a quantity over their current threshold within the 30-day period. Publix employees were

[376] PUBLIX-MDLT8-00079714-716.
[377] PUBLIX-MDLT8-00132730-744.
[378] Id at 731.
[379] Id. at 739.
[380] PUBLIX-MDLT8-00071320-327.
[381] PUBLIX-MDLT8-00071320.

concerned with this because they did not intend for the system to operate in this manner and directed the thresholds be changed to "Yes" from "As Needed." By April 26 (approximately three days after the meeting), 5,000 orders did not ship due to threshold limitations. In response, Publix changed the thresholds back to "As Needed." That was supposed to be temporary, while they increased some family group thresholds "so when we turn them back to Yes, we are using more accurate levels." However, thresholds were still set to "As Needed" on May 9, 2018.[382]

Due Diligence and Flagged Orders, Threshold Increases

In a September 8, 2016 email to Pharmacy Supervisors and Pharmacy Operations Managers, Hewell described some of the differences in the new program that included (i) thresholds based on a rolling 30-day purchase period and not a calendar month (pharmacies can hit their threshold anytime in a month and multiple times per month) and (ii) the system looks for orders that are above average or that deviate from a normal ordering pattern and it rejects anomalies. Hewell's email also provided direction on how to confirm if an order is suspicious, explaining that during pharmacy visits, the Pharmacy Supervisor should review prescription dispensing history for controlled substances (making reference to the Pharmacy R & P Guide) to determine if the pharmacy is dispensing suspicious or "red flag" prescriptions; review monthly controlled substance reporting to determine if the pharmacy is trending high in any of the dispensing categories; and refer to the Manual Inventory Adjustment weekly reporting to see if the pharmacy is making routine inventory updates which may indicate theft.[383]

The Hewell email also advised that if the order is not suspicious, the Pharmacy Supervisor should consider having the pharmacy's threshold increased if there is a business need and provides the steps necessary for the threshold to be increased. Hewell further explained that if an order is deemed suspicious, the Pharmacy Operations Manager and Chris Hewell must be notified immediately.[384] Finally, in the email Hewell explains what is not suspicious and therefore not reportable to DEA including order errors and explainable deviations (new patients, new prescribers, closed pharmacy nearby, etc.).[385]

From 2018, at the start of centralization, until two diversion analysts were hired in 2019, Jennifer Warren and Jillanne Smith were responsible for reviewing all flagged orders and diversion analytics for all Publix pharmacies in the United States (over 1,300 stores).[386] In 2019, the evaluation of orders of interest were shifted from the Pharmacy Supervisors to Compliance (Diversion Analysts), and diversion analysts were responsible for reviewing and investigating flagged orders. The first two diversion analyst employees were hired in 2019.[387] Jennifer Warren was technically the first diversion analyst hired. Eventually there were five total.[388] The two analyst positions hired in 2019 were responsible for all stores throughout the Publix chain.[389] By 2021, Publix had five reviewers (four analysts and one manager) for the entire chain.[390] The five analysts work with the Pharmacy Supervisors.[391]

[382] PUBLIX-MDLT8-00071321.
[383] PUBLIX-MDLT8-00147628-629.
[384] PUBLIX-MDLT8-00147628-629.
[385] PUBLIX-MDLT8-00147628-629.
[386] Smith Depo., at 274:8 – 277:25 (Nov. 15, 2022).
[387] Smith Depo., at 183-184 (Nov. 15, 2022).
[388] Smith Depo., at 183:16 – 185:2 (Nov. 15, 2022).
[389] Smith Depo., at 184-189 (Nov. 15, 2022).
[390] Smith Depo., at 187:18–189:16 (Nov. 15, 2022).
[391] Warren Depo. at 255:5 – 23 (Nov. 11, 2022).

In a joint Pharmacy Operations and Corporate compliance resource proposal in April 2019, two diversion analyst positions were requested. The document stated the purpose of the analyst position is to:

> "…evaluate controlled substance orders that meet certain order parameters for potential risk of diversion. These positions will analyze purchasing and dispensing activity, along with other available data to determine if an order is in fact suspicious or not. The position will monitor receiving exceptions and assist in the evaluation of tote and item level receiving issues, escalating potential diversion upon discovery. This position will assist with diversion analytics and significant loss analysis and determination."[392]

This was Publix's first somewhat dedicated position intended to review and conduct due diligence on orders of interest.

Training

In 2018, Publix created a formal training document for Pharmacy Supervisors concerning the evaluation of threshold increases. In the document, titled "*Controlled Substance Threshold Training for Pharmacy Supervisors*," there is a best practices section that is described as a "… recap of best practices for reviewing and approving threshold increase requests. Under the subsection "Review Store Growth," one of the questions that is suggested to be asked is, "Has there been a change in overall store environment?" The guidance provides three questions that include, "New HCP Practice Open?; Competitor Closing?; File Buys?"[393] These examples are not necessarily reasons or excuses for increasing a threshold but instead may give reason to do a more in-depth investigation into what is happening at the store level. For instance, each of these circumstances (new HCP Practice open nearby, competitor closing, file purchases) may also be a reason to stop or cancel orders from being shipped and not to increase the threshold, and as such require a deeper inquiry. Some rogue HCPs prescribe large quantities of controlled substances illegally and pharmacies involved in diversion close and will sell their prescription files, providing false validation of suspect prescriptions/patients to the pharmacy that purchased the files. This false validation also brings an increase in controlled substance prescriptions that can ultimately cause a request for an increase in threshold. These circumstances open another avenue of investigation rather than justify a threshold increase. This ambiguity makes it even more important that detailed guidance on how to analyze and evaluate the information be provided to those charged with due diligence responsibilities.

One critical instruction that is missing from the document is guidance that directs the Pharmacy Supervisor to review dispensing records of the pharmacy, including data concerning physicians that prescribe large quantities of controlled substances and other drugs of abuse such as benzodiazepines and muscle relaxants, determining the top prescribers of controlled substances and their specialties by drug/strength, and determining if those practitioners prescribe significantly more high dose opioids (oxycodone 30 mg) than low dose opioids (oxycodone 5 mg or 10 mg). It is concerning that the one report (practitioner dispensing data) that could best help decide if a threshold increase is justified is not included in the criteria necessary to evaluating thresholds.

Notably, there was no standardized formal training for pharmacists (or technicians) at the store level concerning red flags analysis, corresponding responsibility, or fraudulent prescriptions before 2019.[394] This type of training would assist the pharmacist in evaluating controlled substance prescriptions and could help stop invalid/illegitimate prescriptions from being dispensed, thereby thwarting drug

[392] PUBLIX-MDLT8-00132692 – 704.
[393] PUBLIX-MDLT8-00130894-895
[394] PUBLIX-MDLT8-00119095; PUBLIX-MDLT8-00079714.

seekers from obtaining medication that would not be used for a legitimate medical purpose, and ultimately decreasing the orders placed by the pharmacy.[395] This type of training would ultimately support the effective operation of the SOM.

Reporting Suspicious Orders

Chris Hewell was responsible for reporting suspicious orders to DEA until sometime on or about August 2018 when that responsibility was transferred to Publix legal counsel (Adam Maingot).[396] The first suspicious order ever reported to DEA was in 2018 when Publix reported 19 suspicious orders.[397]

In the report documenting the 1st quarter 2017 compliance team meeting, it was reported that no suspicious orders were reported to DEA through the system. The team discussed a recent ALJ opinion concerning, "… wholesaler responsibilities in monitoring the system that may affect upcoming DEA Guidance."[398] The 2nd Quarter 2017 memo reported no suspicious orders sent to DEA through the system. The team discussed an 11th Circuit case affirming the previously discussed ALJ opinion describing certain responsibilities in monitoring the system, including the creation and retention of documents substantiating the reasons supporting the increase in orders for scheduled drugs, and whether pharmacies are required to file with the DEA a notice of unusual purchasing activity even if they can document the reasonable explanations for such increases. The memo further stated that they would contact Chris Hewell to determine what Publix is documenting to date, and make him aware of the substantiation requirements.[399] In the third Quarter 2017 compliance team meeting, there were no suspicious orders reported to DEA but the team discussed the *Masters* case and the duty to create and retain documentation, and whether Publix is required to report to DEA a notice of unusual purchasing in the system even if it can document reasonable explanations for an increase. Jillanne Smith was going to meet with Chris Hewell about Publix documentation process.[400]

In August of 2018, Jillanne Smith provided Publix leadership with a proposal for four controlled substances projects noting that some of the tasks described therein were already in progress and "some need[ed] to be kicked off very soon."[401] One of the four listed projects was the "SOM" project, the objective of which was to " identify and implement a new SOM solution to improve effectiveness of compliance with DEA regulations. Ultimately, centralize the analysis of orders, identification of suspicious orders, internal reporting, and DEA/state reporting when required."[402] There were six key deliverables listed all with suggested timelines ranging from August 2018-February 2019. Shockingly, "Dpt. resource capacity" was listed as a constraint to achieving these important deliverables geared towards finally getting Publix compliant with the DEA regulations in late 2018, thirteen years after it started distributing controlled substances.[403] Specifically, the document reviewed by both Smith and Hewell states that one (of the two) compliance analyst will be "about 70% focused on Controlled Substances through year end and then additional resources may be necessary. . .".[404] One compliance analyst for the entire country with a focus on controlled substance compliance only 70% of the time.

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[395] Smith Depo., at 416: 9 – 419:7 (Nov. 15, 2022); see also PUBLIX-MDLT8-00119095; PUBLIX-MDLT8-00072578-579; PUBLIX-MDLT8-00058475-483; PUBLIX-MDLT8-00058515-588.
[396] Hewell Depo., at 128:19 – 129:3 (Nov. 4, 2022).
[397] Hewell Depo., at 128:19 – 129:3 (Jul. 25, 2023); see also Hewell Depo., at 28:9 – 30:15 (Jul. 25, 2023).
[398] PUBLIX-MDLT8-00147789 - 790
[399] PUBLIX-MDLT8-00147793-794
[400] PUBLIX-MDLT8-00147791-792
[401] PUBLIX-MDLT8-00088571-577.
[402] Id. at 577.
[403] Id.
[404] Id.

Analysis of the Publix E-Supply Link System

The system in place in Period 3 was upgraded to an algorithm-based system. The most significant change from Period 2 was the addition of a 17-test algorithm that could measure unusual size, pattern, and frequency. Through at least 2018, however, the system was only running one test out of the 17, and that test was for volume/size. Although this system became operational in 2016, not one suspicious order was filed with DEA until 2018. The technical problems with the system combined with inadequate resources and training, and the absence of formalized processes and policies undermined the ability of the system to work as an effective suspicious order monitoring system.

The Period 3 system still had major flaws, failed to comply with 21 CFR 1301.74(b), and failed to maintain effective controls against diversion. Similar to the system in Period 2, E-Supply Link operated as a threshold-based system flagging for volume only and disregarded frequency and substantial deviation from a normal ordering pattern. Volume-based thresholds only monitor for one of the three criteria established in 21 CFR 1301.74(b). Therefore the Period 3 system during this time period was not compliant. And, similar to the system in Period 2, the system in Period 3 was volume based for total quantity of dosage units ordered and failed to consider the individual drug strengths ordered.

The policies, procedures and training related to processes surrounding threshold breach in Period 3 still did not provide a uniform methodology to investigate the breach and determine why it occurred and whether the cause was legitimate or suspicious. It also did not explain what procedures should be taken to investigate the breach. Training and policies released during this time period were focused on how to request and investigate/justify threshold increase. The guidance documents published by Publix discuss what happens when a threshold breach occurs and how to submit a threshold change request to justify additional threshold quantity but makes no reference to Pharmacy Supervisors determining if the threshold breach and the corresponding order is suspicious. In late 2018, the investigative portion of due diligence was turned over to two employees who were not pharmacists to make the determination of whether an order is suspicious and by 2019 the section that reviewed orders of interest had five employees (for more than 1,000 stores). The resources used to evaluate orders during this time period were clearly inadequate even though some suspicious orders were being reported.

In short, from 2016 to 2020, the system utilized by Publix to identify suspicious orders had many weaknesses that were never overcome. Of significant importance, the failure of the system during Period 3 was even recognized internally by the Publix compliance team. In a July 31, 2018, memo documenting a 2nd quarter 2018 compliance team meeting, Karl Zillgitt wrote (concerning the suspicious order metric) that there were no 2nd quarter suspicious orders reported to DEA. He then documented a discussion about the system between pharmacy compliance team members and stated that they believed "**it does not work**."[405] Zillgitt wrote, "*All of the algorithms (red flags) that can be triggered on the system have been shut down except for 2 relating to the size of the order, so that only a couple of orders were stopped last year. Vendor does not want to work with Publix in making their program work on Publix's system. Also, even if an order were stopped by the Suspicious ordering system, the store could simply purchase the drugs from the wholesaler. Thus, the team believed that this metric should be removed*."[406] These statements reflect the consensus of those individuals charged by Publix with ensuring controlled substance regulatory compliance, i.e., those with the most in-depth knowledge of the inner workings of the Publix SOM at the time, and as such, it supports my opinion that Publix never had an effective SOM system at least prior to June 2020.

[405] PUBLIX-MDLT8-0014779-800.
[406] PUBLIX-MDLT8-00147800.

Period 4: June 2020 – Present

Order Insight (Third-Party System)

In January 2018, Publix employees received orientation/training from Order Insight which was described by a Publix employee as, "…an inventory management solution selected by Publix to assist in maintaining optimal inventory levels in the pharmacy. Their proprietary algorithms set correct reorder points and quantities to meet the inventory needs each day."[407]

By August/September 2018, Publix was shopping for a new system and started negotiations with Order Insight ("OI") to provide SOM support.[408] In August 2018, Publix began to draft a requirements document for the deployment of a new system.[409] A *Scope Document* dated August 14, 2018 listed the objective of the project as: "Identify and implement a new SOM solution to improve effectiveness of compliance with DEA regulations. Ultimately, centralize the analysis of orders, identification of suspicious orders, internal reporting, and DEA/state reporting when required."[410] An August 22, 2018, Business Requirements document described the system functional requirements as: "The system shall evaluate EDI 850 Purchase Orders for suspicious orders, defined by 'Suspicious Order Threshold Business Rules,' when received from the client's Pharmacy Practice Management System and before splitting or forwarding the order to suppliers for fulfilment."[411]

Publix began review of an agreement with OI that would allow OI to conduct purchase order routing/monitoring, 340B integration and suspicious order monitoring (via algorithm) in approximately November 2018.[412] The OI system was created and tested in 2019 and 2020. Publix contracted with Order Insight, started building the system in 2019, and finished rolling out the system to pharmacies in May/June 2020.[413] The OI system was not operational until approximately two years after the Publix compliance team had expressed their belief that the prior system did not work.[414]

Since 2020, Publix has utilized OI as their SOM platform.[415] OI replaced E-Supply Link and was fully implemented in August 2020.[416] Publix switched platforms because OI provides more functionality than E-Supply Link, including additional scrutiny of orders with regard to forecasted demand and daily, weekly and monthly thresholds on a rolling cadence.[417] Because OI can maintain multiple levels of thresholds (e.g., one-day, seven-day and 30-day), which could not be accomplished with E-Supply Link, Publix can increase or decrease thresholds for drug groups or single NDCs. Furthermore, while E-Supply Link required manual set-up and maintenance for new stores, drug groups and thresholds, OI provides automated set-up and maintenance for new stores using a "similar locations model." OI also provides more flexibility around thresholds for drug groups/categories and NDCs. Another improvement with OI is that it evaluates orders made to outside/third-party vendors such as McKesson and Anda; this feature

[407] PUBLIX-MDLT8-00142687 – 729.
[408] PUBLIX-MDLT8-00072085; PUBLIX-MDLT8-00072021-023.
[409] PUBLIX-MDLT8-00071921 – 1934; PUBLIX-MDLT8-00072367 – 382; PUBLIX-MDLT8-00072402 – 2419.
[410] PUBLIX-MDLT8-00086388.
[411] PUBLIX-MDLT8-00072086-2097.
[412] PUBLIX-MDLT8-00072600-621; PUBLIX-MDLT8-00142749 – 768 (signed agreement dated January 11, 2019); see also PUBLIX-MDLT8-00086956 - 958 (Order Insight Buy Summary dated January 3, 2019).
[413] Warren Depo, at 240:6 – 24 (Nov. 11, 2022).
[414] PUBLIX-MDLT8-00147800.
[415] Hewell Depo., at 181:6 – 181:3 (Nov. 4, 2022).
[416] DEA-T711CC-00010900-905.
[417] Hewell Depo., at 181:19 – 182:6 (Nov. 4, 2022).

was unavailable with E-Supply Link.[418] Finally, OI integrates analytical tools that are intended to improve efficiency from E-Supply Link, which was stand-alone.[419]

According to Publix materials provided to me, the OI platform operates in the following manner.

- Inventory management software generates a product request to meet a pharmacy's forecasted demand. Employees/pharmacists can also manually request products.
- Schedule II product requests are reviewed and approved by the CSOS administrators prior to the order being received by the warehouse. Prior to warehouse receipt, the orders are reviewed by the OI system that either flags or clears an order.
- Flagged orders are reviewed by a Compliance Analyst. The orders are run through the system that is designed to detect unusual size, frequency or deviating substantially from a normal pattern. The system is designed to detect orders that exceed anticipated demand (thresholds) and orders that are flagged by OI algorithm tests (size, pattern, frequency).
- Once flagged, the order is omitted without regard for whether it is suspicious or not. The compliance analyst reviews/investigates each flagged order/order of interest to determine whether it is suspicious and must be reported or whether credible evidence supports the conclusion that the order is not suspicious.
- The analyst uses dispensing history, forecasted demand, min/max order points, current BOH, prescription information, inventory adjustments, stores local market/business evaluation (formulary change, storm/hurricane, clinic opening/closing, pharmacy acquisition and industry evaluation (recalls, shortages)) among other data points.
- Documents supporting the decision are maintained in the OI system, internal network drives, and in summary case files.[420]

Hewell confirmed that orders of interest identified by the OI system were reviewed and investigated by Diversion Analysts[421] that were responsible for conducting due diligence on flagged orders and determining whether they are suspicious and reported to DEA. The notes generated from the review would be saved in a folder on the Publix T-Drive.[422]

In an Upshur-Smith SOM Questionnaire in July 2020, Publix described their SOM investigative process as follows: "The flagged order is queued for review and investigation by the Pharmacy Compliance Department as an order of interest. A compliance analyst investigates each order of interest and either confirms the order should be reported to the DEA as suspicious; or obtains credible evidence to conclude the order is not suspicious. Supporting document is maintained in the SOM system, internal network drives and in the summary case report."[423] The internal network drives are the T-Drives and the summary case reports would be a folder that contains the queries run and documentation that would be relevant to the order of interest.[424] There is one summary case file for every order reported, and there could be more for orders that are investigated and then determined not to be suspicious. The earliest date of a summary report in the folder is August 2018,[425] before implementation of the OI platform. In September 2020 Publix discovered a bug in EnterpriseRX that "… designates unsolicited C2 order and

[418] Hewell Depo., at 213:10 – 214:6 (Nov. 4, 2022).
[419] DEA-T711CC-00010900-905.
[420] DEA-T711CC-00010900-905; see also DEA-T711CC-00010923-926.
[421] Publix only had two diversion analysts beginning in 2018 with that number being expanded in to five in 2020. These 2-5 diversion analysts were responsibility for reviewing all Publix suspicious orders for the entire country.
[422] Hewell Depo., at 114:11 – 117:17 (Jul. 25, 2023).
[423] PUBLIX-MDLT8-00080510.
[424] Warren Depo., 257:14 -259:2 (Jul. 11, 2022).
[425] Warren Depo., 260:21 -261:11 (Jul. 11, 2022).

Non-C2 orders within the system." OI acknowledged that they included the unsolicited orders for accumulation, but they do not trigger alerts for unsolicited orders as they have already been processed and ordered.[426]

I have not been provided with specific tests related to the algorithm utilized in the current OI system during Period 4, nor have I been provided with any ARCOS data or other transaction data to determine whether the OI SOM is executed in a manner that maintains effective controls against diversion. However, it appears that the OI system contains all of the components that would be necessary to operate an adequate SOM system.

Summary: Analysis and Conclusion

In the preceding analyses, I described the systems claimed by Publix to comply with the suspicious order identification and reporting requirements of 21 CFR 1301.74(b), and their ability to maintain effective controls against diversion. As I have described above, it is my opinion that throughout the reporting period from 2005 to 2020, Publix did not have a compliant SOM system that met the criteria for compliance with 21 CFR1301.74(b) and therefore Publix failed to maintain effective controls against the diversion of controlled substances as required by their registration in 21 USC §823, thereby contributing to the diversion of controlled substances in Cobb County, Georgia.

Controlled Substance Prescriptions Dispensed Without Resolving Red Flags

As part of my review of materials in this case, I reviewed a draft of the expert report of Carmen Catizone. Mr. Catizone opines as to thousands of controlled substance prescriptions dispensed by each Defendant despite the presence of unresolved red flags. He concludes that Defendants failed to identify, investigate, resolve, and document how each red flag was resolved, if at all, before dispensing the prescriptions. To a reasonable degree of professional certainty, Mr. Catizone's conclusions confirm my conclusion that the Defendants failed to implement effective methods to identify suspicious orders and prevent them from being shipped to their pharmacies.

CONCLUSION

Based upon my review of all of the information available to me and as described herein, including but not limited to the Defendants' SOMs, the Defendants failed to maintain effective controls against diversion because their SOMs show their due diligence efforts fell woefully short of a reasonably prudent self-distributing pharmacy. The procedures in their SOMs did not adequately take into consideration all three components in the due diligence analysis—the order, the customer, and the conditions—and the Defendants failed to monitor, detect, report, and stop suspicious orders. Based on my review of the Defendants' SOMs I am confident that none of these programs were effective at monitoring, detecting, or stopping diversion for the relevant time period, and instead allowed controlled substances to be distributed to pharmacies throughout Cobb County unchecked. Therefore, I conclude that the distribution practices of the Defendants caused, and were a substantial factor in causing, the pharmaceutical opioid epidemic in Cobb County.

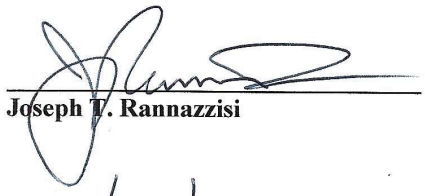
As self-distributing pharmacy corporations, the Defendants had a key advantage—they could monitor and review the dispensing activities of their pharmacy customers without barriers or roadblocks common to third-party distributors. Yet the Defendants inexplicably failed to use that advantage to help

[426] PUBLIX-MDLT8-00080982 – 983.

them analyze and detect suspicious orders. Instead, they provided superficial oversight and monitoring, thereby allowing their obligation to conduct corresponding responsibility falter.

For these reasons and the reasons stated herein, it is my opinion that Defendants caused and were a substantial factor in causing the pharmaceutical opioid epidemic in Cobb County.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information, or upon request of counsel.



Joseph T. Rannazzisi

01/24/2024

Date

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Curriculum Vitae (CV)

SUMMARY STATEMENT

Joseph T. Rannazzisi retired from the United States Drug Enforcement Administration (DEA) on October 31, 2015 after serving over 29 years in drug law enforcement. From June 2005 until retirement, he held the position of Deputy Assistant Administrator of the DEA Office of Diversion Control. In that capacity, Mr. Rannazzisi supervised DEA's efforts to prevent, detect and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate distribution channels. Mr. Rannazzisi was responsible for overseeing and coordinating major controlled substance diversion and clandestine laboratory investigations; the drafting and promulgating of federal regulations; testifying before Congressional committees; establishing drug production quotas; and maintaining liaison with the pharmaceutical industry, international governments, state governments, federal agencies, and with state and local law enforcement agencies. He provided regulatory oversight and supervised the inspection and investigation of all businesses that import, export, manufacture, distribute or dispense controlled substances and listed chemicals to ensure compliance with regulatory requirements related to drug and facility security, recordkeeping and accountability. He was the United States competent authority for controlled substances and listed chemicals and supervised U.S. representatives attending meetings organized by the International Narcotics Control Board (INCB) and the Commission on Narcotic Drugs (CND).

Mr. Rannazzisi is a nationally recognized speaker and instructor and has provided training concerning illicit drugs, pharmaceuticals, pharmaceutical control, corresponding responsibility, security, chemicals, synthetic drugs and clandestine laboratories to hundreds of audiences representing law enforcement, attorneys, judges, professional organizations, pharmaceutical industry executives and employees, community groups, Congress, government officials and international partners that represented law enforcement, compliance and regulatory control agency counterparts. He has provided continuing education to more than 9000 pharmacists and practitioners on all aspects of pharmaceutical controlled substance diversion. He earned a Bachelor of Science Degree in Pharmacy from Butler University and is a registered pharmacist in the State of Indiana. He earned a *Juris Doctor* from the Detroit College of Law at Michigan State University and is a member of the State Bar of Michigan.

EMPLOYMENT HISTORY

Due Diligence Compliance, LLC, Annandale, Virginia

President; June 2017 to Present

- Provide professional consulting services to law firms, state law enforcement/regulatory agencies and professional organizations related to the manufacture, distribution and dispensing of pharmaceutical controlled substances and the manufacture and distribution of listed chemicals.
- Review operating procedures to determine compliance with Federal and state laws and regulations concerning drug and facility security, recordkeeping and accountability.
- Provide policy guidance that ensures appropriate diversion prevention measures to stop the movement of controlled substances and listed chemicals into the illicit marketplace.

- Educate physicians, pharmacists and other health care professionals on their legal obligations under the Federal Controlled Substances Act.

AlphaSix Corporation, Sterling Virginia

Director of Pharmaceutical Compliance and Enforcement; April 2016 to May 2017

- Assisted in the development of IT solutions that identify controlled substance diversion for state regulators, law enforcement agencies and private sector clients.
- Provided consulting services for select DEA registrant classes who handle controlled substances and listed chemicals to ensure compliance with Federal/state statutes and regulations.

United States Drug Enforcement Administration

Deputy Assistant Administrator, Office of Diversion Control, Arlington, Virginia: 2006 - 2015

Outreach and Advocacy

- Developed and promoted strategies, legislative priorities, policies, and the annual budgets of the ODC for submission to the United States Congress. Testified before U.S. House of Representatives and Senate in more than 30 hearings on a variety of topics within the jurisdiction of the Office of Diversion Control, including anabolic steroid trafficking, drug control, prescription drug trafficking trends and abuse, methamphetamine and chemical control, opiates and pain management, heroin, marijuana, emerging synthetic drugs, regulatory control and administrative actions, and registrant investigations and inspections.

- Coordinated, supervised and conducted outreach efforts to the public and registrants. Provided more than 500 presentations to community groups, professional organizations and regulatory boards that represented healthcare and law, as well as the manufacturing and distribution sectors, and Federal and state organizations regarding a wide range of matters within the jurisdiction of the Office of Diversion Control.

- Conceived, developed and provided implementation oversight over the DEA Nationwide Prescription Drug Take-Back Initiative, including solicitation of support and coordination of national media campaign, educational outreach, and development of procedures for each event. This initiative was designed to provide the public with opportunities to dispose of medicines safely and anonymously. This campaign emphasized the drug abuse problem in the United States and the need for federal legislation that would allow the public to dispose of controlled substances. Federal law was enacted shortly after the first take-back event.

- Designed and implemented reorganization of Office of Diversion Control. Established infrastructure and processes necessary to proactively identify compliance violations by registrants, thoroughly and fairly investigate potential violations of law and regulations, and utilize appropriate administrative, civil or criminal sanctions to correct violations. The reorganization of the Office of Diversion Control assisted in striking a balance between achieving the goals of the diversion control program while ensuring a sufficient amount of controlled substances available for the legitimate medical, scientific and industrial needs of

the United States. As a result of reorganization, compliance inspections increased by 528% and administrative compliance actions increased by 86%.

Regulatory Compliance

- Responsible for periodic review of regulations, policies and procedures to determine whether change is necessary to address compliance/diversion trends. Directly supervised and defended the promulgation of major rules and regulations.

- Promulgated processes and procedures designed to monitor regulatory compliance by registrants. Procedures are followed by all DEA personnel when conducting registrant investigations and compliance inspections.

- Developed and implemented policies and procedures designed to identify diversion trends, and develop appropriate targets and investigative strategy. Ensured field investigators and special agents were provided appropriate oversight and guidance regarding case development.

- Provided strategic direction regarding appropriate courses of action when regulatory violations are substantiated, ranging from letters of admonition and memorandums of agreement to administrative hearings that could result in revocation of registration.

Enforcement Operations

- Exercised delegated authority to seek administrative sanctions against DEA registrants for violations of the law and regulations, including suspension or revocation of registration. Principal advisor to DEA Administrator regarding settlement negotiations in relevant administrative, civil, and criminal actions concerning registrants.

- Provided strategic guidance as Executive Director, National Methamphetamine and Pharmaceutical Initiative (NMPI) to a nationwide board comprised of federal and state law enforcement, legal counsel, and community leaders dedicated to developing and implementing policies to eradicate methamphetamine and synthetic drug production and pharmaceutical diversion, trafficking and abuse in the United States.

Deputy Chief, Office of Enforcement Operations, Operations Division, Arlington, Virginia: 2004-2005

- Supervised and provided resource support for all domestic and international criminal and forfeiture investigations related to the trafficking of controlled substances.

Deputy Director, Office of Diversion Control, Arlington, Virginia: 2004-2004

- Provided assistance to the Deputy Assistant Administrator of the Office of Diversion Control related to pharmaceutical and chemical regulatory investigations.

Assistant Special Agent in Charge, Detroit Field Division, Michigan: 2002-2004

- Supervised and provided investigative guidance to five drug enforcement groups comprised of approximately 70 employees including special agents and state and local task force officers,

as well as an administrative support section with responsibility for a multi-million dollar budget. The enforcement groups conducted a wide range of criminal investigations into the activities of large drug trafficking organizations
that operated domestically and abroad. Supervised the activities of the Detroit REDRUM [homicide] Task Force and a federal, state and local housing task force.

- Authorized and supervised enforcement operations that included undercover operations, seeking and executing search warrants, arresting individuals, conducting electronic surveillance including telecommunications interception [wiretap] and preparing investigations and evidence for trial. Ensured that investigations had the appropriate amount of personnel and financial resources to proceed to successful completion.

Staff Coordinator/Section Chief, Dangerous Drugs and Chemicals Section: 2001-2002

- Supervised thirteen supervisory special agents and diversion investigators who coordinated all DEA domestic and international synthetic drug manufacturing/trafficking investigations and precursor chemical trafficking investigations. Responsible for providing appropriate policy guidance and continual resource support to investigations and initiatives to ensure successful outcomes. Liaison to law enforcement agencies, competent authorities within foreign governments, and the International Narcotics Control Board.

Group Supervisor, Detroit Field Division, Michigan: 1997-2001

- Supervised a Federal task force that consisted of twenty special agents, task force officers and administrative support personnel who investigated violations of the Controlled Substances Act.

Special Agent, Detroit Field Division, Michigan: 1988-1997

- Conducted complex criminal investigations of significant drug trafficking organizations that operated domestically and abroad.

Diversion Investigator/Special Agent, Indianapolis Resident Office, Indiana: 1986-1988

- Investigated and inspected potential violations of the Controlled Substances Act by corporations, businesses, and medical practitioners. Identified potential weaknesses in the registrant drug delivery system due to physical security weaknesses or non-compliance with 21CFR and attempted to correct such violations in order to prevent controlled substance diversion into the illicit marketplace.

Veterans Health Administration

Staff Pharmacist, In-Patient Services, Indianapolis, Indiana: 1984-1986

- Provided drug therapy advice to practitioners to improve patient care. Dispensed medications and prepared admixtures pursuant to practitioner orders for administration to patients.

EDUCATION

Bachelor of Science Degree in Pharmacy from Butler University

Juris Doctor from Detroit College of Law at Michigan State University

LICENSES / CERTIFICATION

Registered Pharmacist in the State of Indiana

Member of the State Bar of Michigan

PROFESSIONAL EXPERIENCE

Testimony before Congress:

U.S. House of Representatives Judiciary Committee March 16, 2004,
"The Anabolic Steroid Control Act of 2004"

U.S. Senate Caucus on International Narcotics Control July 13, 2004,
"The Abuse of Anabolic Steroids and Their Precursors by Adolescent Amateur Athletes"

U.S. House of Representatives Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources November 18, 2004,
"Law Enforcement and the Fight against Methamphetamine"

U.S. House of Representatives Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources July 26, 2005,
"Fighting Meth in America's Heartland: Assessing the Impact on Local Law Enforcement and Child Welfare Agencies"

U.S. House of Representatives Government Reform Committee on Regulatory Affairs September 13, 2005, *"Status of the Efforts of the FDA and DEA in Regulating Schedule II Prescription Painkillers, Specifically OxyContin and Other Opioid Analgesics"*

U.S. House of Representatives Judiciary Committee, Subcommittee on Crime Terrorism and Homeland Security September 27, 2005,
"HR 3889 - The Methamphetamine Epidemic Elimination Act of 2005 (The Drug Enforcement Administration's Effort to Combat Methamphetamine)"

U.S. Congressional Caucus to Fight and Control Methamphetamine September 28, 2005,
"The Administration's Efforts in Addressing the Manufacture, Distribution and Abuse of Methamphetamine"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health and Subcommittee on Environment and Hazardous Materials October 20, 2005,
"Comprehensively Combating Methamphetamine: Impact on Health and the Environment"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations December 13, 2005,

"Safety of Imported Pharmaceuticals: Strengthening Efforts to Combat the Sales of Controlled Substances over the Internet"

U.S. House of Representatives Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy and Human Resources June 16, 2006,
"Synthetic Drug Control Strategy"

U.S. House of Representatives Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy and Human Resources July 26, 2006,
"Prescription Drug Abuse: What is being done to address this New Drug Epidemic?"

U.S. Senate Judiciary Committee May 16, 2007,
"Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking"

U.S. House of Representatives Judiciary Committee, Subcommittee on Crime, Terrorism and Homeland Security July 12, 2007,
"The Drug Enforcement Administration's Regulation of Medicine"

U.S. Senate Committee on Finance September 18, 2007,
"Breaking the Methamphetamine Supply Chain: Law Enforcement Challenges"

U.S. Senate Judiciary Committee December 4, 2007,
"Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities"

U.S. House of Representatives Judiciary Committee, Subcommittee on Crime Terrorism and Homeland Security June 24, 2008,
"Online Pharmacies and the Problem of Internet Drug Abuse"

U.S. House of Representatives Judiciary Committee, Subcommittee on Crime Terrorism and Homeland Security June 18, 2009 (Changed to a Members Briefing),
"Take Back Disposal Legislation"

U.S. Senate Judiciary Committee, Subcommittee on Crime and Drugs September 24, 2009,
"Body Building Products and Hidden Steroids: Enforcement Barriers"

U.S. Senate Homeland Security and Government Affairs Committee, Subcommittee on Federal Finance Management, Government Information, Federal Services and International Security September 30, 2009,
"A Prescription for Waste, Controlled Substance Abuse in Medicaid"

U.S. Senate Special Committee on Aging, March 24, 2010,
"The War on Drugs Meets the War on Pain: Nursing Home Patients Caught in the Crossfire"

U.S. Senate Caucus on International Narcotics Control, April 13, 2010,
"The Status of Meth: Oregon's Experience Making Pseudoephedrine Prescription Only"

U.S. Senate Special Committee on Aging, June 30, 2010,
"Drug Waste and Disposal: When Prescriptions Become Poison"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health, July 22, 2010, *"Hearing on Pending Public Health Legislation"*

U.S. Congressional Prescription Drug Abuse Caucus, September 22, 2010,
"Public Congressional Forum on Prescription Drug Abuse, Prescription Drug Monitoring Programs (PDMPs) and a Proposed PDMP Compact Between State Governments"

U.S. Senate Caucus on International Narcotics Control April 6, 2011,
"The Dangers of Synthetic Cannabinoids and Stimulants"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health, July 21, 2011, "*Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues*." Mr. Rannazzisi submitted a statement for the record/written testimony.

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Commerce, Manufacturing, and Trade, March 1, 2012,
"Prescription Drug Diversion: Combating the Scourge"

U.S. Senate Caucus on International Narcotics Control, July 18, 2012,
"Responding to the Prescription Drug Abuse Epidemic"

Senate Committee on Homeland Security and Governmental Affairs, June 24, 2013,
"Curbing Prescription Drug Abuse in Medicare"

U.S. Senate Caucus on International Narcotics Control, September 25, 2013,
"Dangerous Synthetic Drugs"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health, April 7, 2014, "*Improving Predictability and Transparency in DEA and FDA Regulation*"

U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, April 29, 2014, "*Examining the Growing Problems of Prescription Drug and Heroin Abuse*"

U.S. Senate Caucus on International Narcotics Control, May 14, 2014,
"America's Addiction to Opioids: Heroin and Prescription Drug Abuse"

U.S. Senate Caucus on International Narcotics Control, May 5, 2015, *"Improving Management of the Controlled Substance Quota Process"*

U.S. Senate Caucus on International Narcotics Control, June 24, 2015 for a hearing, *"Cannabidiol: Barriers to Research and Potential Medical Benefits"*

U.S. Senate Homeland Security and Government Affairs Committee, November 28, 2017 roundtable discussion (in hearing format), *"Restoring DEA Enforcement Power Over Drug Distributors"*

AWARDS and HONORS

Presidential Award for Meritorious Executive in the Senior Executive Service, 2008: Presented for sustained superior accomplishment in management of programs and for noteworthy achievement of quality and efficiency in the public service.

Honorary Doctor of Pharmacy, Oklahoma State Board of Pharmacy, 2014

National Association of Boards of Pharmacy Lester E. Hosto Distinguished Service Award - 2015

PUBLICATIONS

The Tennessean, Opinion, "Ex-DEA agent: Consequences of Marsha Blackburn's opioid law not 'unintended' " (Nov. 4, 2018), https://www.tennessean.com/story/opinion/2018/11/04/consequences-marsha-blackburn-opioid-law-not-unintended/187578002/

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21 CFR § 1301.13(e)	21 U.S.C. § 802(21)	21 U.S.C. § 824	O.C.G.A. § 16-13-36
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21 CFR § 1301.71(b)(14)	21 U.S.C. § 812(b)(2)-(5)	21 U.S.C. § 827(d)	O.C.G.A. § 26-4-115
21 CFR § 1301.74(b)	21 U.S.C. § 822(a)	21 U.S.C. § 832(a)	
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21 CFR § 1307.11	21 U.S.C. § 823(d)		
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United States District Court, Northern District of Ohio, Eastern Division, In Re National Prescription Opioid Litigation - Cobb County v. Purdue Pharmacy, L.P., et al., MDL No. 2804, Case No. 17-md-2804, Publix Supermarkets, Inc. Supplemental Objections and Responses to Plaintiff's Interrogatories to Chain Pharmacy Defendants (June 16, 2021)

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Kroger Defendants' Objections and Responses to Track 8 Plaintiff's Requests for Production to New Chain Pharmacy (Dec. 23, 2021)

Expert Reports and Materials

Carmen Catizone Report (Jan. 24, 2024)
SLCG, Opioid Shipments to Pharmacies in Cobb County, Georgia retail (ARCOS DATA)
SLCG, Annual Reports of Opioid Distribution by Distributor/Cobb County/Pharmacy 2006-2014
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Transcript and Exhibits from Deposition of Brehm, Levi (Mar. 11, 2021)
Transcript and Exhibits from Deposition of Brice, Shannon (Aug. 3, 2023)
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Transcript and Exhibits from Deposition of Reisinger, Matthew (Mar. 2, 2022)
Transcript and Exhibits from Deposition of Rusk, Dain (Oct. 6, 2023)
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Transcript and Exhibits from Deposition of Springer, Jerry (July 22, 2021) and Errata (Nov. 15, 2021)
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116 Cong. Rec. 977-78 (Jan. 23, 1970)

Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 , Decision and Order, 77 Fed. Reg. 62316 (Oct. 12, 2012)

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https://en.wikipedia.org/wiki/Cobb_County,_Georgia

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PUBLIX-MDLT8-00058515-588
Publix-MDLT8-00059249
PUBLIX-MDLT8-00065740
Publix-MDLT8-00065877
PUBLIX-MDLT8-00067262
PUBLIX-MDLT8-00067275 – 7306
PUBLIX-MDLT8-00067275-307
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PUBLIX-MDLT8-00067907-909
Publix-MDLT8-00069637
PUBLIX-MDLT8-00071320-327
PUBLIX-MDLT8-00071321
PUBLIX-MDLT8-00071323 – 327
PUBLIX-MDLT8-00071921 – 1934
PUBLIX-MDLT8-00072021-023
PUBLIX-MDLT8-00072085
PUBLIX-MDLT8-00072086-2097
PUBLIX-MDLT8-00072367 – 382
PUBLIX-MDLT8-00072402 – 2419
PUBLIX-MDLT8-00072578-579
PUBLIX-MDLT8-00072600-621
Publix-MDLT8-00073491 – 492
PUBLIX-MDLT8-00073500-502
PUBLIX-MDLT8-00076593-596
PUBLIX-MDLT8-00079714-716
PUBLIX-MDLT8-00080510
PUBLIX-MDLT8-00080982 – 983
PUBLIX-MDLT8-00086388
PUBLIX-MDLT8-00086956 - 958
PUBLIX-MDLT8-00088571-577
PUBLIX-MDLT8-00098667
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PUBLIX-MDLT8-00126452-916
PUBLIX-MDLT8-00130893 – 895
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PUBLIX-MDLT8-00132323
PUBLIX-MDLT8-00132692 – 704
PUBLIX-MDLT8-00132730-744
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PUBLIX-MDLT8-00142687 – 729
PUBLIX-MDLT8-00142749 – 768
PUBLIX-MDLT8-00143405
PUBLIX-MDLT8-00143498 -514
PUBLIX-MDLT8-00143536
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PUBLIX-MDLT8-00147776-777
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PUBLIX-MDLT8-00147781-782
PUBLIX-MDLT8-00147783-7784
PUBLIX-MDLT8-00147789 - 790
PUBLIX-MDLT8-0014779-800
PUBLIX-MDLT8-00147791-792
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